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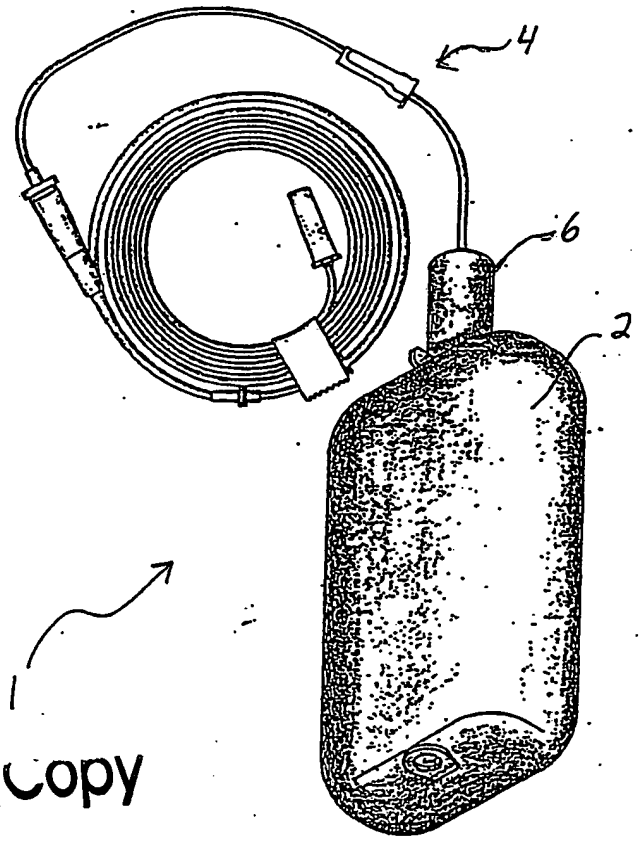
(54) Title: FLUID CONTAINER AND CONNECTION COMPONENT

(57) Abstract

An enteral fluid delivery system (1) is disclosed having a fluid container (2) with a pierceable seal (10) covering an opening to the container (2). A connection component (6) connects an administration set (4) to the fluid container (2). The connection component (6) includes a hollow tube (48, 132) that is connected to the administration set (4) at one end and has a spike (50, 130) at the other end. During storage and transportation, spike (50, 130) is aligned with and positioned slightly away from the seal (10). In use, spike (50, 130) is linearly movable to pierce the seal (10) thereby communicating the fluid in the container (2) through the tube (48, 132) to the administration set (4). Spike (50, 130) is prevented from inadvertently moving to pierce the seal (10) by retaining means. The retaining means may be selectively disengaged thereby allowing the spike (50, 130) to move to pierce the seal (10). In the preferred embodiment of the invention, the fluid container (2) and the administration set (4) are provided together in a set with the container (2) prefilled with fluid and the connection component (6) connecting the container (2) and the administration set (4) with the spike (50, 130) retained in position aligned with and positioned slightly away from seal (10).



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FLUID CONTAINER AND CONNECTION COMPONENT

TECHNICAL FIELD

The invention relates to fluid containers and connection components for connecting the fluid containers to a fluid delivery system and more particularly relates to fluid containers and connection components for connecting fluid containers containing enteral feeding fluids to an enteral feeding fluid administration set.

BACKGROUND ART

Enteral feeding systems typically include a container of enteral feeding fluid, an enteral feeding tube for delivering the enteral feeding fluid to a patient's intestinal system and a connection component system for connecting the enteral feeding tube to the fluid container. The connection component system typically includes an administration set including tubing connecting the fluid container to the enteral feeding tube. The administration set is connected to the fluid container through a connection component and is connected to the enteral feeding tube through a port mounted on the feeding tube. Typically, the enteral feeding tube remains in place within the patient for several days at a time while the enteral fluid container and the administration set are changed every 24 hours.

It has been the usual practice in enteral feeding fluid delivery systems to provide a separate enteral feeding fluid container and a separate administration set that are connected through the connection component at the time the fluid container and the administration set are changed. This procedure has several problems.

First, there is the danger of cross contamination of the feeding fluid by the clinician. Because the fluid container and the administration set are separate, they must be connected through the connection component. While connecting the fluid container to the administration set, the surfaces on

the connection component are susceptible to being touched, and thereby contaminated, by the clinician. Then as the connection component connects the fluid container to the administration set, the contaminated surfaces of the connection component are placed in contact with the enteral fluid thereby contaminating the fluid.

Second, when changing the empty fluid container, remnants of the fluid within the container leak from the container. This leaked fluid produces objectionable consequences affecting cleanliness and health.

Further, having separate fluid containers and administration sets requires separate packaging, storage and inventories for each. These problems described above are preferably to be avoided.

An example of a typical prior art system is disclosed in European Patent 0281270. There a fluid container and connection component is described in which the fluid container has a pierceable seal and the connection component comprising a hollow spike which is designed to pierce the seal when the connection component is screwed onto the container. The spike is connected to a feeding tube for delivery of fluid from the container. The sealed fluid container has a cap which is removed to permit the container to be connected to the fluid delivery set which comprises the connection component and associated tubing. The delivery set is normally provided in a sterilized package with a removable seal over the spike of the connection component. It is possible for the operator to contaminate the spike of the delivery set when connecting the set to the fluid container.

DISCLOSURE OF INVENTION

According to the present invention there is provided a fluid container having a pierceable seal covering the opening. A connection component is positioned in proximity of the seal. The connection component has a hollow pointed projecting member at one end that is connected to the tubing of an

administration set. When the connection component is positioned in proximity of the seal, the hollow pointed projecting member is aligned with and positioned slightly away from the seal. The pointed projection is movable to pierce the seal thereby communicating the fluid in the container through the hollow projecting member to the administration set tubing. The pointed projection is prevented from inadvertently moving to pierce the seal by retaining means. The retaining means may be selectively disengaged thereby allowing the hollow projecting member to move to pierce the seal as described above.

In the preferred embodiment of the invention, the fluid container and the administration set are provided together in a set with the container prefilled with fluid and the connection component connecting the container and the administration set with the hollow projecting member retained in position aligned with and positioned slightly away from the seal.

The invention is illustrated in the accompanying drawings which show various embodiments of the invention.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a perspective view of the prefilled enteral fluid bag and an administration set connected by a connection component.

Figure 2 is a cutaway and partial cross-sectional view of one embodiment of the invention.

Figure 3 is a plan view of the position housing of the invention of Figure 2.

Figure 4 is a side cross-sectional view of the position housing of Figure 3 along the line labeled 4-4 in Figure 3.

Figure 5 is an end view of the position housing shown in Figure 3.

Figure 6 is a cross-sectional view of the position housing in Figure 3 along the line labeled 6-6 in Figure 4.

Figure 7 is a plan view of the locking tube of the invention of Figure 2.

Figure 8 is a cross-sectional view of the locking tube of Figure 7 along the line labeled 8-8.

Figure 9 is an end view of the locking tube shown in Figure 7.

Figure 10 is a cross sectional view of an alternate embodiment of the seal and connection component of Figure 1.

Figure 11 is a perspective view of the preferred embodiment of the safety stop of the invention.

Figure 12 is a perspective view of an alternate embodiment of the safety stop of the invention.

Figure 13 is a cross-sectional view of an alternate embodiment of the seal and connection component of Figure 1.

Figure 14 is a cutaway and partial cross-sectional view of the embodiment of Figure 13 with the tang aligned with the longitudinal groove.

Figure 15 is a plan view of part of the retaining means of the connection component of Figure 13.

Figure 16 is a cross-sectional view of an alternate embodiment of the invention.

Figure 17 is a cross-sectional view of an alternate embodiment of the invention.

Figure 18 is a partial cutaway and a partial cross-sectional view of an embodiment of the invention.

Figure 19 is a partial cutaway and a partial cross-sectional view of the invention of Figure 18 along the line labeled 19-19 in Figure 18.

Figure 20 is a perspective view of the invention of Figure 18 with the spike shown in phantom.

Figure 21 is a cross-sectional view of the invention of Figure 18 in its collapsed position.

Fig. 22 is part sectional and part perspective view of the container showing the connection component fitted onto the container without piercing the seal.

Fig. 23 is a part sectional and part perspective view of showing the connection component screwed onto the container with the seal pierced.

BEST MODES FOR CARRYING OUT THE INVENTION

Figure 1 shows a system 1 having a fluid container 2 connected to an administration set 4 through a connection component 6. In the preferred embodiment of the invention, the fluid container 2 and the administration set 4 are provided together in a set with the container 2 prefilled with fluid.

Also in the preferred embodiment, the connection component 6 connecting the container 2 and the administration set 4 does not allow the fluid in the container 2 to enter the tubing of the administration set 4 until the system 1 is to be used with a patient. In addition, in the preferred embodiment, the connection component 6 is preconnected to both the container 2 and the administration set 4 and sealed so that the fluid pathway from the fluid container 2 through the connection component 6 to the administration set 4 may not be contaminated by contact with the clinician.

In the system 1 described above, the problems of cross contamination, remnants of the fluid within the container 2 leaking from the container 2 and separate packaging, storage and inventories for each component of the system 1 are eliminated.

Although the fluid container 2 is prefilled with fluid in the preferred embodiment, it is also within the scope of the invention to provide the fluid container 2 without fluid and have the fluid placed in the container 2 at a later time.

In the embodiments described herein, like elements are referred to by like reference numbers. Small variations in the shape of like elements, such as will be readily apparent to and clearly understood by those skilled in the art, may be found from one embodiment to the next. However, the description of an element and its function are equally

applicable whenever the like element is described or referred to throughout this description.

Figures 2 through 10 show the preferred embodiment of the invention. In this embodiment, a hollow seal mount 8 is preferably integrally formed with and extends away from container 2 ending in a seal 10.

Seal mount 8 is preferably molded as part of the container 2. Alternately, seal mount 8 may be a separate piece attached to container 2 by any means as will be well understood to those skilled in the art. In either case, seal mount 8 is roughly cylindrical with a central bore 12 and is made of a semi-rigid thermoplastic material such as polyethylene or a laminated material with oxygen and moisture barrier properties.

A flat disc shaped seal 10 is placed across the distal end of seal mount 8. Throughout this description, proximal refers generally to a direction toward container 2 while distal refers generally to a direction away from container 2. Seal 10 is made of a material that is frangible for a purpose that will be described hereafter. The material of seal 10 is preferably a laminate of plastic and foil as is well understood by those skilled in the art. Seal 10 is sealed to seal mount 8 by means such as heat sealing or other similar means. Fluid present within container 2 is also present in the interior of seal mount 8 in bore 12 proximal to and in contact with seal 10.

Connection component 6 includes a positioning housing 14 that surrounds and is attached to seal mount 8. Positioning housing 14 extends distally beyond seal mount 8. Positioning housing 14 is preferably cylindrical and has a cylindrical bore 16 that extends through positioning housing 14 aligned with the central axis of seal mount 8. Cylindrical bore 16 ends at its proximal end in bore 17 that has a somewhat smaller diameter that bore 16 for a purpose to be described hereafter.

Figures 2 through 6 show views of positioning housing 14. As can be seen, an annular flange 18 extends away from positioning housing 14 at approximately a right angle near the proximal end of positioning housing 14. A flat bottomed annular locking groove 20 extends into and around positioning housing 14 distal and adjacent to flange 18.

A pair of diametrically opposed planar flats 22, 24 extend into positioning housing 14 on opposite sides of positioning housing 14 near the distal end of positioning housing 14. The proximal end of flats 22, 24 forms a right angle.

A generally annular flange 28 extends away from positioning housing 14 at approximately a right angle near the distal end of positioning housing 14. Flange 28 is chamfered on its distal side. Flange 28 has a pair of flats 23, 25 located adjacent and parallel to and a small distance away from flats 22, 24. The proximal surface of flange 28 contacts both flats 22, 24 and the outer surface 34 of positioning housing 14 at a right angle thereby forming a lip of approximately equal height around outer surface 34 and flats 22, 24.

Connection component 6 also includes a spike mount 36. As shown in Figures 7 through 9, a flange 38 is located near the distal end of spike mount 36. Spike mount 36 includes a cylindrical locking tube 40 having central bore 42 that extends proximally away from and at a right angle to flange 38. The proximal end of locking tube 40 has a pair of opposed inwardly directed tangs 44. Tangs 44 preferably extend inwardly from locking tube 40. Tangs 44 each have a width B (Fig. 9) less than the width A of flats 22, 24.

Tangs 44 also each have a contact surface 46. The distance between contact surfaces 46 across bore 42 is equal to or somewhat less than the distance C (Fig. 6) between flats 22, 24 across bore 16.

A hollow cylindrical projecting member 48 extends through flange 38 at a right angle to flange 38 within and concentric

with locking tube 40. Projecting member 48 has an outer diameter somewhat less than the diameter of bore 12. Projecting member 48 ends at one end in a sharp, pointed spike 50.

Projecting member 48 opposite spike 50 extends beyond flange 38 and ends in a connection mount 49. Connection mount 49 is connected to the administration set 4. The connection of connection mount 49 to administration set 4 creates a fluid pathway from administration set 4 through hollow projecting member 48. The method of connecting administration set 4 to connection mount 49 may be of any number of methods well understood in the art including but not limited to solvent bonding, adhesive bonding or a mechanical locking system.

Spike mount 36 and positioning housing 14 are preferably manufactured of a rigid thermoplastic material such as polycarbonate, PVC or ABS.

A semi-rigid strain relief 52, as is well understood in the art, surrounds the connection between the administration set 4 and connection mount 49 to prevent strain caused by movement of the administration set 4 relative to connection component 6 from kinking or breaking the administration set 4 where it is connected to connection mount 49.

In assembling connection component 6, the longitudinal axis of locking tube 40 is aligned with the longitudinal axis of positioning housing 14 so that tangs 44 are aligned with flats 23, 25 on flange 28. Locking tube 40 is moved proximally so that the contact surfaces 46 of tangs 44 move first over the chamfered distal side of flange 28 and then over flats 23, 25 finally coming into contact with flats 22, 24. Because contact surfaces 46 of tangs 44 move over flats 23, 25 instead of over any other portion of the outer edge of flange 28, strain on tangs 44 resulting from being distended while moving over flange 28 is minimized.

With tangs 44 positioned so that contact surfaces 46 contact flats 22, 24, tangs 44 are in their normal unstressed position so that little or no strain is placed on tangs 44 by

contact with positioning housing 14. Locking tube 40 is prevented from proximal movement by contact between tangs 44 and the walls of positioning housing 14 that are formed at right angles to flats 22, 24 as described above. Locking tube 40 is prevented from distal movement by contact between tangs 44 and the proximal side of flange 28 at flats 23, 25.

With tangs 44 seated on flats 22, 24, spike 50 is positioned adjacent to but not in contact with seal 10. In this position, the system 1 may be stored or transported ready for use but without fear that spike 50 may inadvertently move into contact with and rupture seal 10 or that spike mount 36 will separate from positioning housing 14.

When it is desired to use the system 1, locking tube 40 is rotated about its longitudinal axis thereby moving tangs 44 across the edge 32 of flats 22, 24 and onto the outer surface 34 of positioning housing 14. This allows locking tube 40 to be moved proximally toward flange 18. Contact between tangs 44 and flange 28 prevents locking tube 40 from moving distally. The consequence of locking tube 40 moving distally is that locking tube 40 separates from positioning housing 14.

As locking tube 40 is moved toward flange 18, spike 50 is moved into contact with and ruptures seal 10. Further proximal movement of locking tube 40 causes projecting member 48 to move into an interference fit with bore 17 so that leakage of fluid from within container 2 past projecting member 48 and seal 10 is prevented.

Locking tube 40 is moved proximally until tangs 44 enter groove 20. At this time, contact between tangs 44 and flange 18 prevents further proximal movement of locking tube 40. Contact between tangs 44 and the wall formed at the distal edge of inward surface 26 and positioning housing 14 prevents distal movement of locking tube 40. Consequently, locking tube 40 is "locked" into position with spike 50 projecting through seal 10 and projecting member 48 in an interference fit with bore 17 so that leakage of fluid past seal 10 is

prevented. In this position, fluid within container 2 passes through projecting member 48 to administration set 4.

Figure 10 shows an alternate embodiment of the invention. In this embodiment, as described above, seal mount 8 is attached to and extends from container 2. Seal 10 is preferably integrally mounted to the distal end of seal mount 8. Seal mount 8 also has a bore 12 extending through seal mount 8 and in contact with seal 10. In this way fluid within container 2 is in contact with seal 10 through bore 12.

Connection component 6 includes a positioning housing 56 that surrounds seal mount 8 and extends distally beyond seal mount 8. Positioning housing 56 is preferably rigid, cylindrical, hollow and ends at its distal end in a bore 58 that is tapered, narrowing in a proximal direction. A cavity 60 is formed within positioning housing 56 between bore 58 and seal 10. Cavity 60 generally has an inner diameter somewhat larger than the diameter of bore 58 except for a portion distal to seal 10 where cavity 60 narrows to a bore 61 having a diameter slightly smaller than the projecting member 48.

A hollow projecting member 48 extends through bore 58, ending at its proximal end in a spike 50. Spike 50 is contained within cavity 60 and is concentrically aligned with seal 10.

A tapered flange 62 extends away from projecting member 48 a short distance distal to spike 50. Once assembled into positioning housing 56, flange 62 prevents spike 50 from moving distally out of cavity 60.

A second tapered flange 64 extends around projecting member 48 distal to the first flange 62. Flanges 62 and 64 have diameters slightly larger than the diameter of bore 58.

Projecting member 48 opposite spike 50 extends beyond flange 38 and ends in a connection mount 49 as described above. Connection mount 49 is connected to the administration set 4. The connection of connection mount 49 to administration set 4 creates a fluid pathway from administration set 4 through hollow projecting member 48. A

strain relief 52 surrounds the connection of connection mount 49 to administration set 4.

Projecting member 48 may move along its longitudinal axis through bore 58 constrained in its proximal movement by contact between flange 64 and the distal edge of bore 58 and constrained in its distal movement by contact between flange 62 and the proximal edge of bore 58.

A stop flange 66 extends away from projecting member 48 at a right angle near the distal end of projecting member 48. Flange 66 has an outer diameter sufficiently large to prevent further proximal movement when flange 66 contacts the distal face of positioning housing 56.

A safety stop 68 is placed between the distal edge of bore 58 and flange 66. In the preferred embodiment shown in Figure 11, safety stop 68 is partially cylindrical and surrounds a significant portion of projecting member 48. Alternately, as shown in Figure 12, safety stop 68 is cylindrical and entirely surrounds a portion of projecting member 48. In this embodiment, safety stop 68 contains a frangible portion 70 that allows safety stop 68 to be removed from around projecting member 48. In either embodiment, a tab 72 extends away from safety stop 68 to enable it to be grasped between the thumb and forefinger. Safety stop 68 and tab 72 are preferably integrally made of a rigid material such as plastic so that with safety stop 68 in position between the distal edge of bore 58 and flange 66, projecting member 48 is prevented from moving proximally toward the positioning housing 56.

In the preferred embodiment shown in Figure 11, safety stop 68, when in place, encircles only a portion of projecting member 48. Grasping and pulling tab 72 removes safety stop 68 from around projecting member 48.

In the embodiment shown in Figure 12, safety stop 68 entirely surrounds projecting member 48. In this embodiment, safety stop 68 includes a frangible portion 70 that breaks the continuous safety stop 68 at frangible portion 70. With

safety stop 68 in place in continuous circumference around projecting member 48, grasping and twisting tab 72 causes frangible portion 70 to break. Then, safety stop 68 may be removed from around projecting member 48 by pulling on tab 72.

In assembling the system 1, positioning housing 56 is placed around seal mount 8 and connected to container 2. The administration set 4 is attached to connection mount 49 within a strain relief 52 so that a fluid pathway is formed through the spike 50, projecting member 48 and administration set 4 within strain relief 52 thereby connecting the spike 50 with the administration set 4. The container 2 is preferably prefilled with enteral fluid.

The safety stop 68 is applied around projecting member 48 between flanges 62 and 66. Spike 50 is inserted within cavity 60 aligned with seal 10. Safety stop 68 is then in position between the distal face of positioning housing 56 and flange 66 so that projecting member 48 is securely positioned against movement through bore 58.

At this time, as shown in Figure 10, the spike 50 is aligned with but is spaced a small distance away from seal 10. Safety stop 68 prevents proximal movement of projecting member 48 thereby preventing the spike 50 from moving proximally into contact with, and thereby rupturing, seal 10.

When the system 1 has been attached to an enteral feeding tube and it is desired to provide fluid from within container 2 to the enteral feeding tube through the administration set 4, safety stop 68 is removed, as described above, by grasping and pulling tab 72. With safety stop 68 removed, projecting member 48 is moved proximally toward container 2 thereby bringing the spike 50 into contact with seal 10. Further proximal movement of projecting member 48 forces the spike 50 through seal 10 so that a fluid pathway is provided from container 2 through projecting member 48 into the administration set 4. In this position, projecting member 48 is in an interference fit with bore 61 so that fluid within container 2 may not leak past projecting member 48.

Figures 13 through 15 show another alternate embodiment of the invention. In this embodiment, seal mount 8 is preferably integrally formed with and extends away from container 2 ending in a seal 10. In this way fluid within container 2 is in contact with seal 10. Seal mount 8 includes a bore 12 as described above.

Connection component 6 includes a positioning housing 74 that surrounds seal mount 8 and extends distally beyond seal mount 8. Positioning housing 74 is preferably cylindrical, hollow and has a central bore 76.

At least one locking channel 78 (Figure 15) is located on the outer surface 80 of positioning housing 74 at the distal end of positioning housing 74. Locking channel 78 extends into positioning housing 74 a small distance. If two tangs 44 are used, as will be described hereafter, an additional locking channel 78 may be positioned on the outer surface 80 of positioning housing 74 opposite the first locking channel 78.

Each locking channel 78 consists of two transverse grooves 82 and 90 connected by a longitudinal groove 88. The transverse grooves 82 and 90 may contain narrow portions 84 and 92, respectively, for a purpose to be described hereafter.

Connecting component 6 includes a locking tube assembly 96. Locking tube assembly 96 has a flange 98 located at its distal end. A projecting member 48 extends through flange 98. Projecting member 48 is hollow and has an outer diameter smaller than the diameter of flange 98. Projecting member 48 ends at its proximal end in a spike 50. Spike 50 is contained within bore 76 and is concentrically aligned with seal 10.

The distal end of projecting member 48 is in fluid communication with administration set 4. A strain relief 52 surrounds the connection between projecting member 48 and administration set 4.

Locking tube assembly 96 includes a cylindrical locking tube 100 that surrounds and is concentric with projecting member 48. The proximal end of locking tube 100 has at least

one inwardly directed tang 44 having a height about equal to the depth of locking channel 78. When two locking channels 78 are placed on positioning housing 74, an additional inwardly directed tang 44 is placed on locking tube 100 opposite the first tang 44.

Locking tube 100 is placed around positioning housing 74 so that tang 44 is positioned within locking channel 78. Locking tube 100 has a length so that when tang 44 is in transverse groove 90, spike 50 is aligned with but spaced away a small distance from seal 10.

As described above, transverse groove 90 contains a narrow portion 92. When tang 44 is moved into the most transverse end 94 of transverse groove 90, tang 44 must be moved through the narrow passage created by narrow portion 92. Once tang 44 has moved past narrow portion 92, tang 44 is "locked" in position between narrow portion 92 and the most transverse end 94 of transverse groove 90. In this position, shown in Figure 13, contact between the proximal edge of transverse groove 90 and tang 44 prevents locking tube 100, and consequently projecting member 48, from proximal movement. This prevents spike 50 from contacting and rupturing seal 10.

Tang 44 may be moved past narrow portion 92 into alignment with longitudinal groove 88 by rotating the locking tube 100 relative to the positioning housing 74. When tang 44 is aligned with longitudinal groove 88, as shown in Figure 14, locking tube assembly 96 and consequently projecting member 48 may be moved proximally. This brings the spike 50 into contact with seal 10. Further proximal movement of projecting member 48 forces the spike 50 through seal 10 so that a fluid pathway is provided from container 2 through projecting member 48 and strain relief 52 into the administration set 4.

Once a fluid pathway has been created between the container 2 and the administration set 4, tang 44 may be rotated into locking groove 82. As described above, locking groove 82 contains a narrow portion 84. When tang 44 is moved into the most transverse end 86 of locking groove 82, tang 44

must be moved through the narrow passage created by narrow portion 84.

Once tang 44 has moved past narrow portion 84, tang 44 is "locked" in position between narrow portion 84 and the most transverse end 86 of locking groove 82. In this position, contact between the distal edge of locking groove 82 and tang 44 prevents locking tube 100, and consequently projecting member 48, from distal movement which would disrupt the fluid pathway between the container 2 and the administration set 4.

Figure 16 shows an embodiment of the system 1 shown in Figure 1. A seal mount 8 protrudes away from container 2. Seal mount 8 is preferably molded as part of the container 2. Alternately, seal mount 8 may be a separate piece attached to container 2 by any means as will be well understood to those skilled in the art. In either case, seal mount 8 is roughly cylindrical and made of a semi-rigid thermoplastic material such as polyethylene. Seal mount 8 has an inner bore 12 extending proximally from the distal end of seal mount 8.

An annular flange 102 is located along seal mount 8 and extends away from and entirely encircles seal mount 8. Flange 102 is preferably tapered so that the proximal side of flange 102 has a larger outer diameter than the distal side of flange 102. The proximal side of flange 102 forms a lip 104.

Seal mount 8 ends at its distal end in a flat disc shaped seal 10 as described above. Seal 10 extends across the distal end of bore 12. As above, fluid present within container 2 is also present in the interior of seal mount 8 and bore 12 and is in contact with seal 10.

Connection component 6 includes a cylindrical outer housing 106 having a proximal end 108 and a distal end 110. Outer housing 106 has a longitudinal axis aligned with the longitudinal axis of seal mount 8 and is positioned around seal mount 8. The proximal end 108 of outer housing 106 includes an inwardly directed ring 112 that contacts the outer surface of seal mount 8 when outer housing 106 surrounds seal mount 8. Ring 112 is preferably tapered so that the distal

side of ring 112 has a greater diameter than the proximal side of ring 112. The distal side of ring 112 forms a lip 114.

In the preferred version of this embodiment, an additional lip 116 extends inwardly from outer housing 106 a distance distal to ring 112. The distance from lip 114 to lip 116 is equal to or slightly less than the distance from the proximal side of ring 112 to the connection of container 2 to seal mount 8.

A safety stop 68 surrounds seal mount 8 between the body of container 2 and proximal end 108 of outer housing 106. In the preferred embodiment, as described above, safety stop 68 surrounds seal mount 8 for more than half the circumference of seal mount 8. However, alternately, safety stop 68 may entirely surround seal mount 8 and include a frangible portion 70 as described above.

As above, in either case, a tab 72 extends away from safety stop 68 and both are preferably integrally made of a rigid material such as plastic. Safety stop 68 is placed between the proximal side of ring 112 and the connection of container 2 to seal mount 8. Safety stop 68 prevents the outer housing 106 from moving in a proximal direction toward the body of container 2. Grasping and pulling tab 72 removes safety stop 68 from around seal mount 8.

Connection component 6, in this embodiment, includes a hollow projecting member 48 extending from the distal end 110 of connection component 6. Projecting member 48 has an outer diameter somewhat smaller than the diameter of bore 12. The proximal end of projecting member 48 terminates in a spike 50. Spike 50 has a sharp pointed proximal end.

The administration set 4 is connected to connection component 6 at the distal end 20 of connection component 6. A strain relief 52 surrounds the connection between the administration set 4 and connection component 6 and extends distally along the administration set 4 to prevent strain from movement of the administration set 4 from kinking the administration set 4 or from damaging the connection between

the administration set 4 and connection component 6. The connection of connection component 6 to administration set 4 creates a fluid pathway from administration set 4 inside strain relief 52 to the hollow projecting member 48. The method of connecting administration set 4 to connection component 6 may be of any number of methods well understood in the art including but not limited to solvent bonding, adhesive bonding or a mechanical locking system.

In order to prevent leakage of feeding solution, a sealing member 118 extends around projecting member 48 from the distal end 110 of connection component 6. Sealing member 118 surrounds and is concentric with projecting member 48. With the safety stop 68 in place, the proximal end of sealing member 118 contacts the distal end of seal mount 8 so that contact between the proximal end of sealing member 118 and the distal end of seal mount 8 creates a sliding seal. In this way, any fluid within container 2 that passes by the central opening of spike 50 and escapes into the area around spike 50 is retained within sealing member 118.

In assembling the system 1, safety stop 68 is placed around seal mount 8. The longitudinal axis of connection component 6 is aligned with the longitudinal axis of seal mount 8. Outer housing 106 is moved proximally until the proximal side of ring 112 contacts the distal side of flange 102. Continued proximal movement of connection component 6 moves ring 112 over flange 102. The tapered shape of ring 112 and flange 102 facilitates this relative movement. Contact between safety stop 68 and the proximal end of outer housing 106 limits proximal movement of outer housing 106 relative to seal mount 8.

When ring 112 has moved proximally past flange 102, contact between lip 104 and lip 114 prevents connection component 6 from moving distally along and separating from seal mount 8. Also, during assembly, when ring 112 has moved proximally past flange 102, contact between ring 112 and seal mount 8 securely positions outer housing 106 around seal mount

8. As a result of the proximal movement of outer housing 106, sealing member 118 is brought into sealing contact with the distal end of seal mount 8.

In addition, the container 2 is preferably prefilled with enteral fluid. At this time, as shown in Figure 16, spike 50 is aligned with but is spaced a small distance away from seal 10. Safety stop 68 prevents proximal movement of connection component 6 thereby preventing the spike 50 from moving proximally into contact with, and thereby rupturing, seal 10.

When the system 1 has been attached to an enteral feeding tube through administration set 4 and it is desired to provide fluid from within container 2 to the administration set 4, safety stop 68 is removed, as described above, by grasping and pulling tab 72. Safety stop 68 is then removed from around seal mount 8. With safety stop 68 removed, connection component 6 is moved proximally toward container 2 thereby bringing the spike 50 into contact with seal 10. Further proximal movement of connection component 6 forces the spike 50 through seal 10 so that a fluid pathway is provided from container 2 through projecting member 48 and administration mount 52 into the administration set 4.

When connection component 6 has been moved proximally so that spike 50 has ruptured seal 10 and a fluid pathway is provided from container 2 through projecting member 48 into the administration set 4, contact between lip 116 and lip 104 holds connection component 6 in place relative to seal mount 8 and prevents the fluid pathway from being broken. The seal created by sealing member 118 engaging the distal end of seal mount 8 prevents fluid from container 2 from leaking out of connection component 6.

The embodiment of Figure 17 is the embodiment shown in Figure 16 described above without sealing member 118 and with the inclusion of an "O"-ring 120 or other sealing method including but not limited to a lip seal system as is well understood in the art. "O"-ring 120, or the other sealing system used, entirely encircles the distal end of seal mount

8. Except as stated, this embodiment operates as described above in connection with the embodiment shown in Figure 16.

As stated, an "O"-ring 120 or other sealing system is placed entirely around seal mount 8 proximal to the distal end of seal mount 8. "O"-ring 120 forms a seal between the seal mount 8 and outer housing 106 so that any fluid from container 2 that may have found its way into the space within outer housing 106 will not escape outer housing 106.

An alternate embodiment of the invention is shown in Figures 18 through 21. In this embodiment, the container 2 is connected an administration set 4 through a connection component 6 including a first grip tube 122. First grip tube 122 is preferably cylindrical with an outer surface 124 having a high degree of friction that allows the outer surface 124 to be easily gripped. Examples of treatments to the outer surface 124 include knurled, grooved, burnished, molded with small protrusions or other means such as will be clear to those skilled in the art.

Container 2 preferably includes a seal mount 8 that ends in a seal 10 such as is described above. Seal mount 8 preferably includes a flexible annular ledge 152 extending around the periphery of seal 10. First grip tube 122 preferably fits around and encases seal mount 8 and seal 10. First grip tube 122 is attached to container 2 by any suitable means including but not limited to solvent bonding, adhesive bonding or a mechanical locking system.

Connecting component 6 also includes a second grip tube 126. Second grip tube 126 is also preferably cylindrical with an outer surface 128 having a high degree of friction that allows the outer surface 128 to be easily gripped as described above in connection with first grip tube 122.

A conical spike 130 extends away from second grip tube 126 along the longitudinal axis of second grip tube 126. Spike 130 has a hollow connecting tube 132 extending away from the point 134 of spike 130. Spike 130 has an inlet opening 136 at the proximal end of spike 130 near the connecting point

of connecting tube 132 and spike 130. Administration set 4 is attached to the distal end of connecting tube 132 by any number of methods well understood in the art including but not limited to solvent bonding, adhesive bonding or a mechanical locking system. Inlet opening 136, connecting tube 132 and administration set 4 form a fluid path.

A pair of opposed locking tabs 138 extend away from the outer surface 124 of first grip tube 122 at approximately a right angle. Each locking tab 138 has a fin 140 and a lip 142 extending along the distal edge of fin 140.

A pair of opposed locking tabs 144 extend away from the outer surface 128 of second grip tube 126 at approximately a right angle. Each locking tab 144 has a fin 146 and a lip 148 extending along the proximal edge of fin 146.

Fins 140 and 146 preferably extend away from outer surfaces 124 and 128, respectively, at approximately a right angle. Further, fins 140 and 146 may be generally planar or they may be formed in rubber sheet geometry in helical form.

Lips 142 and 148 correspond in shape so that they will mate with each other to form a "lock" as will be described hereafter.

A semi-rigid skirt 150 connects the distal edge of first grip tube 122 with the proximal edge of second grip tube 126. Skirt 150 is preferably made of a relatively thin, for example .010 to .015", polyolefin material such as polyethylene or polypropylene. Skirt 150 may be attached to first and second grip tubes 122 and 126 by any means as will be clear to those skilled in the art. Skirt 150 has sufficient length and rigidity so that in its unstressed position, the proximal end 134 of spike 130 is positioned adjacent to but not in contact with seal 10.

In this embodiment, first and second grip tubes 122 and 126, and locking tabs 138 and 144 are preferably made of a polyolefin material such as polyethylene or polypropylene having a sufficient thickness to be rigid.

In operation, first grip tube 122 and second grip tube 126 are simultaneously grasped and rotated in opposite directions. This causes skirt 150 to twist in a helical fashion (Fig. 20) drawing second grip tube 126 nearer to first grip tube 122. Locking tabs 144 move along a helical path 154 (Fig. 20). As second grip tube 126 moves toward first grip tube 122, the proximal end of spike 130 moves into contact with and ruptures seal 10 (Fig. 21). Fluid present within container 2 flows through inlet opening 136, connecting tube 132 and administration set 4 to the patient.

As first and second grip tubes 122 and 126 continue to be rotated in opposite directions, locking tabs 144 are moved toward a corresponding locking tab 138 until lips 148 ride up over lips 142 and mate to "lock" and thereby prevent second grip tube 126 from rotating in a direction toward first grip tube 122. This prevents second grip tube 126 from moving distally away from first grip tube 122, thereby moving spike 130 out of contact with seal 10 and the fluid within container 2.

When lips 142 and 148 are mated in their locked configuration, spike 130 preferably abuts annular ledge 152 extending around the periphery of seal 10. This abutting relation forms a seal between spike 130 and ledge 152 so that fluid present within container 2 will not flow past spike 130 into the area between first and second grip tubes 122 and 126 that is encased by skirt 150.

Alternately, when lips 142 and 148 are mated in their locked configuration, spike 130 may not placed be in sealing contact with ledge 152. In this embodiment, the combination of spike 130 and ledge 152 forms a silt trap that allows silt collected on or near seal 10 to be washed away from inlet opening 136 by fluid within container 2 leaking past ledge 152 between ledge 152 and spike 130 and carrying the silt. In this way, as spike 130 pierces seal 10, silt is washed away from seal 10 with the leaked fluid.

An alternate embodiment of the invention is shown in Figures 22 and 23. Referring to Figure 22 a container 2 filled with enteral feeding fluid has a foil seal 10. The neck 156 is threaded and receives a connection component 6 in the shape of a cap 158 provided with a hollow projecting member 48 having a spike 50 with a sharp pointed end and a fluid receiving opening 160 facing away from the center. The cap 158 has an airvent 162 with a one way valve 164. An annular ring 166 is screwed onto the neck 156 of the container 2 and occupies a first position 168 in which it is held by means of adhesive. In this position the projecting member 48 cannot pierce the foil seal 10. The tubular projecting member 48 is connected to an administration set 4 through an strain relief 52 shown in part in Figures 22 and 23. The airvent 162 is provided with a removable cap 170.

The adhesive seal of the ring 166 can be broken by a twisting force and the ring 166 screwed down the neck 156 of the container 2 to a second position 172 shown in Figure 23. The cap 158 can then be screwed further down the neck 156 of the container to break the seal 10 and permit fluid to enter the hollow projecting member 48 and the administration set 4.

In this embodiment the stop means comprises an annular ring 166 movable along the threaded portion from a first position 168 to a second position 172, the first position 168 being such that the cap 158 abuts the ring 166 and the projecting member 48 cannot pierce the seal 10, and the second position 172 being such that the cap 158 can be screwed further onto the container 2 whereby the projecting member 48 pierces the seal 10.

The ring 166 may be held in the first position 168 by an adhesive seal which can be broken by a twisting force exerted on the ring 166. Alternatively the stop means may comprise a removable safety stop 68 which can be peeled off the threaded portion of the container 2.

The container 2 and administration set 4 are provided in a sterile package. In use the operator screws the cap 158

onto the container 2 without running the risk of contaminating the connection component 6.

While the instant invention has been described in connection with specific embodiments, it is to be understood that the specific details of the description have been given by means of example only and not for limitation. It is clear that changes and modifications may be made to the description contained herein and still be within the scope of the claims. Further, obvious changes and modifications will occur to those skilled in the art.

CLAIMS

1. An enteral fluid system for attaching to an administration tube set comprising:

a fluid container; and,

means for connecting said fluid container to the administration tube set wherein said means for connecting selectively fluidly connects said fluid container to the administration tube set.

2. The system of claim 1 wherein the administration tube set is connected to said means for connecting, said fluid container is prefilled with fluid and wherein said means for connecting is selected to not fluidly connect said fluid container to the administration tube set whereby the system and administration tube set may be transported and stored.

3. The system of claim 1 wherein said means for connecting comprises:

a frangible seal fluidly connected to said fluid container;

a tube having a longitudinal axis and a proximal and a distal end, said distal end fluidly connected to the administration tube set, said proximal end having a sharp pointed spike, said longitudinal axis aligned with said frangible seal; and,

means for moving said tube along said longitudinal axis so that said spike moves through said seal into fluid contact with fluid within said fluid container thereby creating a fluid pathway from said fluid container through said tube into the administration tube set.

4. The system of claim 3 wherein said means for moving comprises:

a generally cylindrical first member having a proximal and a distal end, said first member also having a central bore with a proximal and a distal end, said first member attached to said fluid container at said proximal end of said first member, said central bore of said first member aligned with said seal, said proximal end of said bore located adjacent to said seal, said distal end of said bore extending through said distal end of said first member;

a generally cylindrical second member having a proximal and a distal end, said second member concentrically encasing a portion of said first member, said second member movable longitudinally along a portion of said first member, said tube contained within said central bore of said second member aligned with said seal;

means for selectively retaining said second member at a first position encasing said first member at said distal end of said first member, whereby said spike is adjacent to but not in contact with said seal;

means for retaining said second member at a second position encasing said first member, said second position located proximal to said first position, whereby said spike penetrates said seal thereby forming a fluid pathway from said fluid container through said tube into the administration tube set; and,

means for allowing said second member to move from said first position to said second position.

5. The system of claim 4 wherein said first member includes said central bore of said first member having a first diameter at said distal end of said bore and a second diameter at said proximal end of said bore, said second diameter of said bore being smaller than said first diameter, said second diameter being approximately equal to the diameter of said tube;

whereby, in said second position, said tube is in an interference fit with said central bore of said first member at said proximal end of said central bore of said first member.

6. The system of claim 4 wherein said means for selectively retaining said second member at said first position, said means for retaining said second member at said second position and said means for allowing said second member to move comprise:

at least one inwardly directed tang extending from the proximal end of said second member into said central bore of said second member; and,

wherein said first member includes:

at least one planar first member flat located at said distal end of said first member a distance from the ultimate distal end of said first member, said first member flat extending in a transverse direction to the longitudinal axis of said first member and forming a right angle at the proximal edge of said first member flat;

an annular groove located along the outer surface of said first member proximal to said first member flat;

a first annular flange extending away from said first member, said first annular flange located proximal and adjacent to said first annular groove, said first annular flange defining the proximal edge of said annular groove;

a second annular flange located at the ultimate distal end of said first member, said second annular flange having a flange flat parallel and adjacent to said first member flat;

whereby in assembling the system, the longitudinal axis of said second member is aligned with the longitudinal axis of said first member so that said tang is aligned with said first member flat on said second annular flange, said second member is moved proximally so that said tang moves over said flange flat on said second annular flange finally coming

into contact with said first member flat on said first member; and,

whereby said second member is prevented from proximal movement by contact between said tang and said right angle at the proximal edge of said first member flat and said second member is prevented from distal movement by contact between said tang and the proximal side of said second annular flange at said flange flat on said second annular flange; and,

whereby, when it is desired to use the system, said second member is rotated about its longitudinal axis thereby moving said tang onto the outer surface of said first member thereby allowing said second member to be moved proximally toward said first annular flange, moving said spike into contact with and rupturing said seal, ultimately moving said tube into an interference fit with said proximal end of said central bore of said first member so that leakage of fluid from within said fluid container past said tube is prevented; and,

whereby said second member is moved proximally until said tang enters said annular groove so that contact between said tang and said first annular flange prevents further proximal movement of said second member and contact between said tang and the distal edge of said annular groove prevents distal movement of said second member.

7. The system of claim 6 wherein the distal edge of said second annular flange is chamfered.

8. The system of claim 4 wherein said means for selectively retaining, said means for retaining and said means for allowing said tube to move comprises:

said first member having at least one locking channel located on the outer surface of said first member at the distal end of said first member, said locking channel

extending into said first member a small distance, said locking channel comprising:

a first transverse groove;

a second transverse groove;

a longitudinal groove connecting said first and said second transverse grooves;

a cylindrical locking tube surrounding and concentric with said tube, said locking tube having a proximal and a distal end, said tube attached to said distal end of said locking tube, said proximal end of said locking tube having at least one inwardly directed tang, said locking tube also having a stop flange located at said distal end of said locking tube, said tube extending through said stop flange, said stop flange having a diameter larger than the diameter of said tube, said locking tube is placed around said first member so that said tang is positioned within said locking channel, said locking tube having a length so that when said tang is in said first transverse groove, said spike is aligned with but spaced away a small distance from said seal,

whereby, contact between the proximal edge of said first transverse groove and said tang prevents said locking tube, and consequently said tube, from proximal movement, thereby preventing said spike from contacting and rupturing said seal;

whereby, said tang is moved into alignment with said longitudinal groove by rotating said locking tube relative to said first member so that when said tang is aligned with said longitudinal groove, said locking tube and consequently said tube may be moved proximally bringing said spike into contact with said seal;

whereby further proximal movement of said tube forces said spike through said seal so that a fluid pathway is provided from said fluid container through said tube and into the administration set;

whereby, once a fluid pathway has been created between said fluid container and the administration set, said tang may be rotated into said second transverse locking groove, so that contact between the distal edge of said second transverse groove and said tang prevents said locking tube, and consequently said tube, from distal movement.

9. The system of claim 8 wherein said first and said second transverse grooves include means for selectively retaining said tang at the ultimate end of said first and said second transverse grooves.

10. The system of claim 9 wherein said means for selectively retaining comprises narrow portions located a small distance from the ultimate end of said first and said second transverse grooves.

11. The system of claim 3 wherein said means for moving comprises:

a first generally cylindrical member having a proximal and a distal end, said first member also having a central bore with a proximal and a distal end, said central bore also having a constricted bore at said distal end of said central bore, said constricted bore having a diameter smaller than the diameter of said distal end of said central bore central bore proximal to said constricted bore, said first member attached to said fluid container at said proximal end of said first member, said central bore of said first member aligned with said seal, said proximal end of said bore located adjacent to said seal;

means for selectively retaining said tube at a first position whereby said spike is adjacent to but not in contact with said seal;

means for retaining said tube at a second position located proximal to said first position, whereby said spike penetrates said seal thereby forming a fluid pathway from

said fluid container through said tube into the administration tube set and whereby said tube is in an interference fit with said central bore of said first member at said proximal end of said central bore of said first member; and,

means for allowing said tube to move from said first position to said second position.

12. The system of claim 11 wherein said means for retaining said tube at a second position includes said central bore of said first member having a first diameter at said distal end of said bore and a second diameter at said proximal end of said bore, said second diameter of said bore being smaller than said first diameter, said second diameter being approximately equal to the diameter of said tube;

whereby, in said second position, said tube is in an interference fit with said central bore of said first member at said proximal end of said central bore of said first member.

13. The system of claim 11 wherein said means for allowing said tube to move from said first position to said second comprises:

a first flange extending away from said tube a short distance distal to said spike, said first flange having a diameter larger than the diameter of said constricted bore;

a second flange extending around said tube distal to said first flange, said second flange having a diameter larger than the diameter of said constricted bore;

whereby said tube may move along its longitudinal axis through said constricted bore constrained in proximal movement by contact between said second flange and the distal edge of said constricted bore and constrained in distal movement by contact between said first flange and the proximal edge of said constricted bore.

14. The system of claim 11 wherein said means for selectively retaining said tube at said first position comprises:

a stop flange extending away from said tube at a right angle near the distal end of said tube, said stop flange having an outer diameter larger than the diameter of said constricted bore to prevent further proximal movement when said stop flange contacts the distal face of said first member at said distal side of said constricted bore; and,

a selectively removable safety stop placed between the distal edge of said constricted bore and said stop flange, said safety stop having means for selectively removing said safety stop from between the distal edge of said constricted bore and said stop flange, said safety stop made of a rigid material so that with said safety stop in position between the distal edge of said constricted bore and said stop flange, said tube is prevented from moving proximally toward the said first member.

15. The system of claim 14 wherein said safety stop is partially cylindrical and surrounds a significant portion of said tube.

16. The system of claim 14 wherein said safety stop is cylindrical and entirely surrounds a portion of said tube, said safety stop including a frangible portion traversing said safety stop in a generally longitudinal direction so that as said frangible portion is broken, said safety tab may be removed from around said tube.

17. The system of claim 14 wherein said safety stop includes a tab extending away from said safety stop to enable said safety stop to be grasped between the thumb and forefinger to facilitate removal from around said tube.

18. The system of claim 3 wherein said means for moving comprises:

a generally cylindrical seal mount protruding away from said fluid container, said seal mount having a proximal and a distal end, said seal mount having an inner bore extending proximally from said distal end of said seal mount, said inner bore in fluid communication with said fluid container;

a frangible seal located at said distal end of said seal mount, said seal extending across the distal end of said inner bore of said seal mount so that fluid present in the interior of said inner bore of said seal mount is in contact with said seal;

a cylindrical outer housing having a proximal end and a distal end, said outer housing having a longitudinal axis aligned with the longitudinal axis of said seal mount, said outer housing positioned around said seal mount, said tube concentrically attached to said outer housing at said distal end of said outer housing so that said tube is aligned with said seal;

means for selectively retaining said outer housing at a first position whereby said spike is adjacent to but not in contact with said seal;

means for retaining said tube at a second position located proximal to said first position, whereby said spike penetrates said seal thereby forming a fluid pathway from said fluid container through said tube into the administration tube set; and,

means for allowing said outer housing to move from said first position to said second position.

19. The system of claim 18 wherein said means for selectively retaining includes a selectively removable safety stop surrounding said seal mount between said fluid container and said proximal end of said outer housing, said safety stop having means for selectively removing said safety stop from around said seal mount, said safety stop

made of a rigid material so that with said safety stop in position around said seal mount, said outer housing is prevented from moving proximally toward the said fluid container.

20. The system of claim 19 wherein said safety stop is partially cylindrical and surrounds a significant portion of said tube.

21. The system of claim 19 wherein said safety stop is cylindrical and entirely surrounds a portion of said tube, said safety stop including a frangible portion traversing said safety stop in a generally longitudinal direction so that as said frangible portion is broken, said safety tab may be removed from around said tube.

22. The system of claim 19 wherein said safety stop includes a tab extending away from said safety stop to enable said safety stop to be grasped between the thumb and forefinger to facilitate removal from around said tube.

23. The system of claim 18 wherein said means for allowing includes:

said seal mount including an annular flange located along said seal mount and extending away from and entirely encircling said seal mount, said annular flange being tapered so that the proximal side of said annular flange has a larger outer diameter than the distal side of said annular flange, the proximal side of said annular flange forming a flange lip; and,

wherein said outer housing includes said proximal end of said outer housing having an inwardly directed ring that contacts the outer surface of said seal mount when said outer housing surrounds said seal mount, said ring being tapered so that the distal side of said ring has a greater diameter than the proximal side of said ring, the distal

side of said ring forming a ring lip, said outer housing also having a second lip that extends inwardly from said outer housing a distance distal to said ring, the distance from said ring lip to said second lip is equal to or slightly less than the distance from the proximal side of said ring to the connection of said fluid container to said seal mount.

24. The system of claim 18 further comprising means for preventing fluid that has moved past said spike into said outer housing from escaping from said outer housing.

25. The system of claim 24 wherein said means for preventing fluid that has moved past said spike into said outer housing from escaping from said outer housing comprises a cylindrical sealing member attached to said distal end of said outer housing and concentric with and surrounding said tube, said sealing mount having a proximal and a distal end, said sealing member having a length so that with said safety stop surrounding said seal mount, said proximal end of said sealing member contacts the distal end of said seal mount so that contact between said proximal end of said sealing member and the distal end of said seal mount creates a sliding seal so that any fluid within said fluid container that passes by said spike and escapes into the area around said spike is retained within said sealing member.

26. The system of claim 24 wherein said means for preventing fluid that has moved past said spike into said outer housing from escaping from said outer housing comprises an "O"-ring entirely encircling said seal mount proximal to the distal end of said seal mount and contacting said outer housing thereby forming a seal between said seal mount and said outer housing so that any fluid from fluid

container that may have found its way into the space within said outer housing will not escape said outer housing.

27. The system of claim 1 wherein said means for connecting comprises:

a seal mount having a proximal and a distal end, said seal mount attached to said fluid container at said proximal end of said seal mount, said seal mount in fluid communication with said fluid container;

a frangible seal attached to the distal end of said seal mount so that said seal is in fluid communication with said seal mount;

a generally cylindrical first grip tube having a proximal and a distal end, said first grip tube also having means for allowing said first grip tube to be grasped, said first grip tube surrounding and encasing said seal mount and said seal, said first grip tube aligned with said seal;

a generally cylindrical second grip tube having a proximal and a distal end, said second grip tube also having means for allowing said second grip tube to be grasped;

a conical spike extending away from said second grip tube along the longitudinal axis of said second grip tube, said spike having an inlet opening at the proximal end of said spike;

a hollow connecting tube having a proximal and a distal end, said connecting tube extending away from the apex of said spike, said connecting tube fluidly connected to said inlet opening in said spike at said proximal end of said connecting tube, said distal end of said connecting tube connected to the administration set so that said inlet opening, said connecting tube and the administration set form a fluid path;

flexible means for connecting said first grip tube to said second grip tube, said flexible means for connecting twisting in a helical direction as said second grip tube is rotated relative to said first grip tube thereby decreasing

the longitudinal distance between said first and said second grip tubes so that said spike is brought from a position adjacent to but not in contact with said seal into contact with and rupturing said seal, thereby allowing fluid within said seal mount to pass through said fluid path; and,

means for selectively retaining said second grip tube at a rotated position relative to said first grip tube.

28. The system of claim 27 wherein said means for selectively retaining comprises:

a pair of opposed first locking tabs extending away from the outer surface of said first grip tube at approximately a right angle, each of said locking tabs having a first fin and a first lip extending along the distal edge of said first fin;

a pair of opposed second locking tabs extending away from the outer surface of said second grip tube at approximately a right angle, each of said second locking tabs having a second fin and a second lip extending along the proximal edge of said second fin, said second lips corresponding in shape to said first lips;

whereby in operation, said first grip tube and said second grip tube are simultaneously grasped and rotated in opposite directions causing said means for connecting to twist in a helical fashion thereby drawing said second grip tube nearer to said first grip tube; and,

whereby said second locking tabs move along a helical path until said second lips ride up over said first lips and mate to "lock" and thereby prevent said second grip tube from rotating in a direction toward said first grip tube thereby preventing said second grip tube from moving distally away from said first grip tube and moving said spike out of contact with said seal and the fluid within said fluid container.

29. The system of claim 27 wherein said first and said second fins are generally planar.

30. The system of claim 27 wherein said first and said second fins are formed in rubber sheet geometry in helical form.

31. The system of claim 27 wherein said flexible means for connecting comprises a semi-rigid skirt connecting the distal edge of said first grip tube with the proximal edge of said second grip tube, said skirt made of a thin, flexible material, said skirt attached to said first and said second grip tubes along the peripheral edges of said first and said second grip tubes, said skirt having sufficient length and rigidity so that in its untwisted position, said apex of said spike is positioned adjacent to but not in contact with said seal and when said second grip tube is rotated relative to said first grip tube, said apex of said spike is brought into contact with and ruptures said seal;

whereby in operation, said first grip tube and said second grip tube are simultaneously grasped and rotated in opposite directions causing said skirt to twist in a helical fashion thereby drawing said second grip tube nearer to said first grip tube.

32. The system of claim 27 wherein said seal mount includes a flexible annular ledge extending around the periphery of said seal.

33. The system of claim 3 wherein said means for moving includes:

said fluid container having a threaded connection;

a closure cap comprising a cap shaped component body including a circular wall portion and a cylindrical threaded portion extending proximally therefrom, said threaded

portion threadedly connecting to said threaded connection on said fluid container, said tube extending proximally from said wall portion, said wall portion also having an air vent situated on the wall portion, said threaded connection of the container having movable stop means in a first position on said fluid container, said stop means being located so that said connection component can be screwed onto said fluid container but said projecting member cannot pierce the seal, wherein in use, said stop means can be removed to permit said connection component to be screwed further onto said fluid container whereby said projecting member pierces said seal.

34. The system of claim 33 wherein said stop means comprises an annular ring movable along said threaded portion from a first position to a second position, said first position being such that said cap abuts said ring and said projecting member cannot pierce said seal, and said second position being such that said cap can be screwed further onto said fluid container whereby said projecting member pierces said seal.

35. The system of claim 34 wherein said ring is held in said first position by an adhesive seal which can be broken by a twisting force exerted on said ring.

36. The system of 33 wherein said stop means is removable from said fluid container.

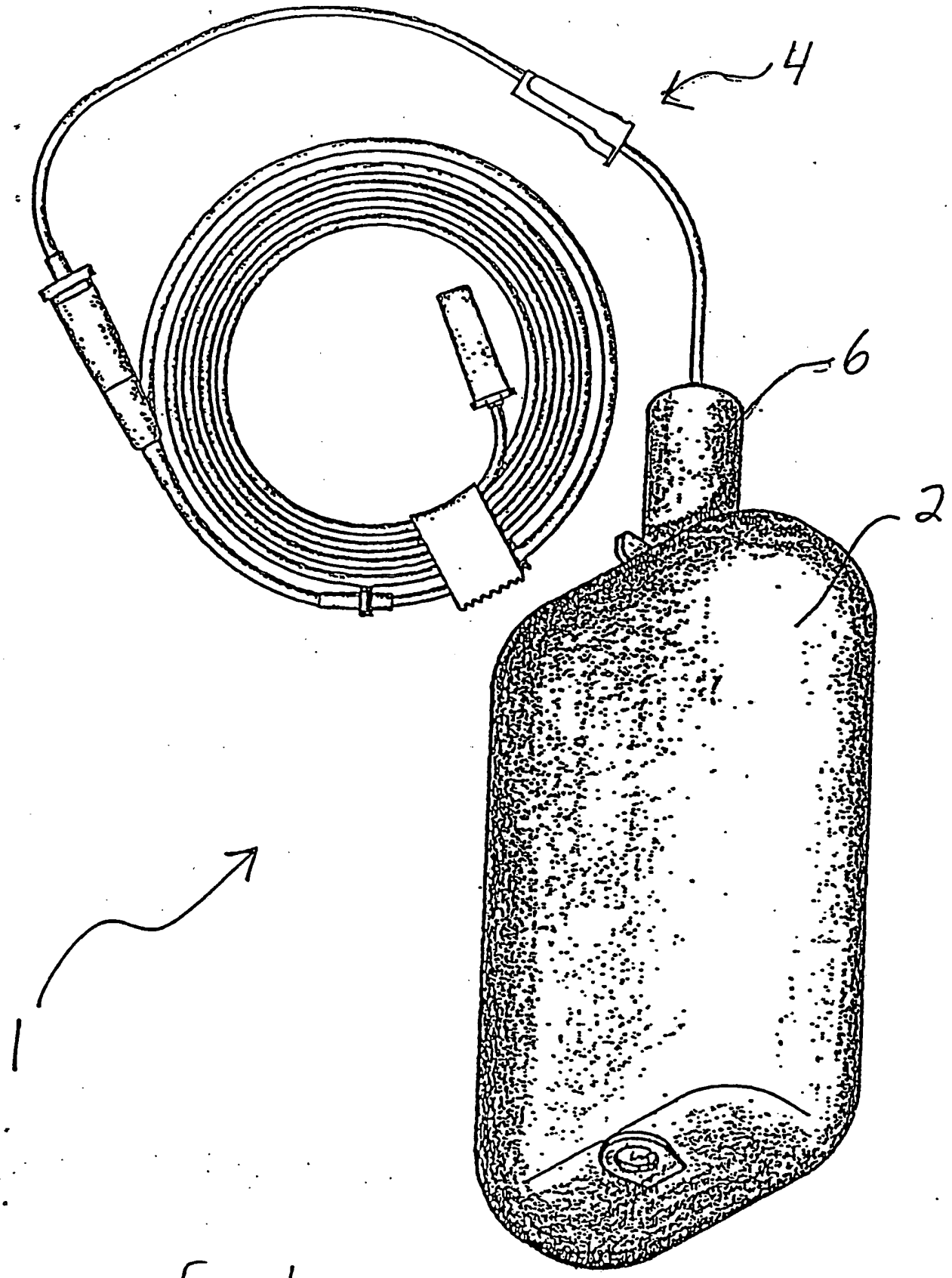


Fig. 1

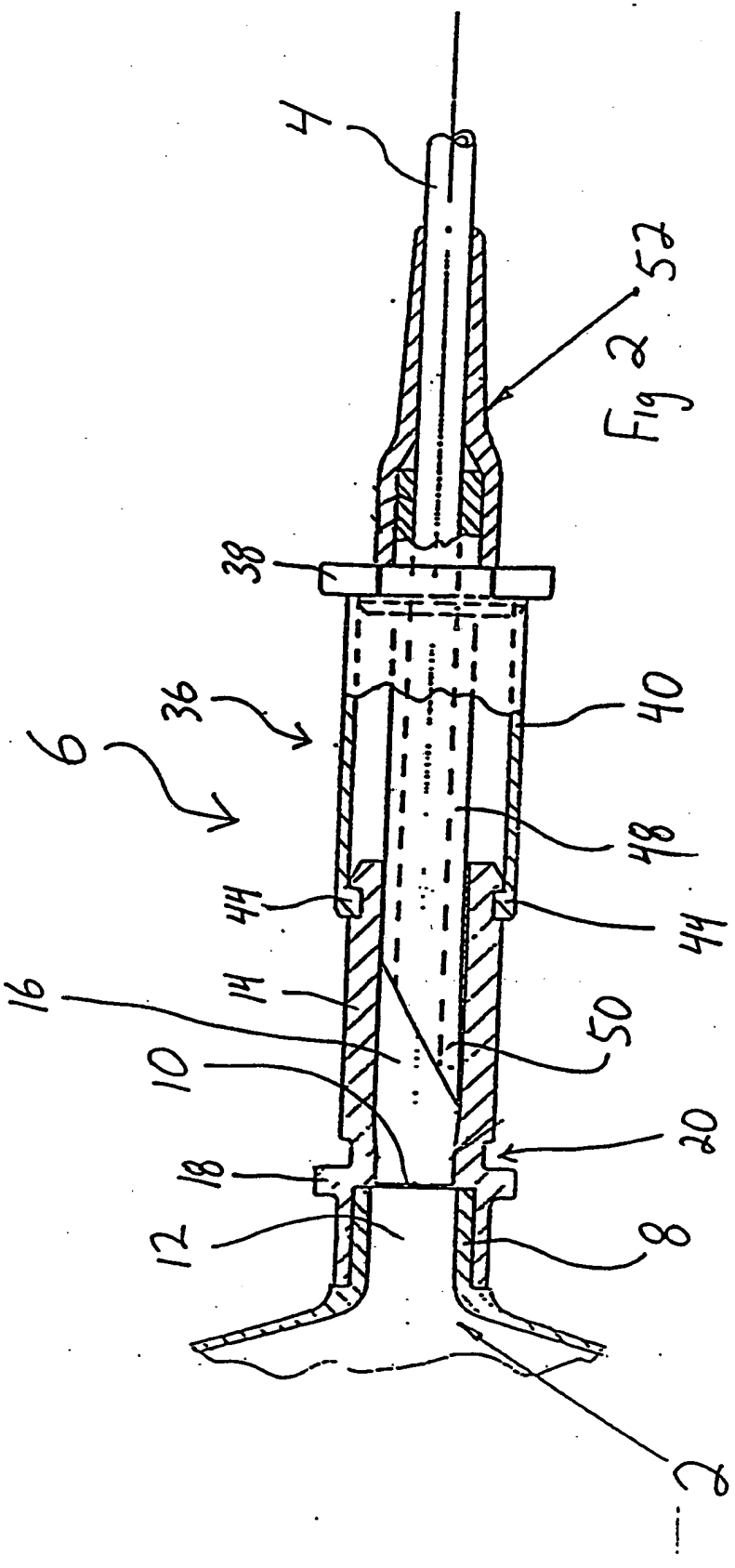


Fig 2

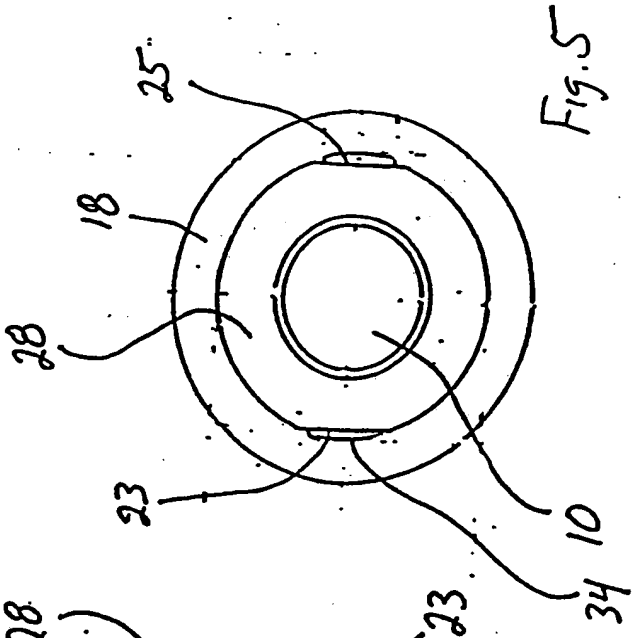


Fig. 5

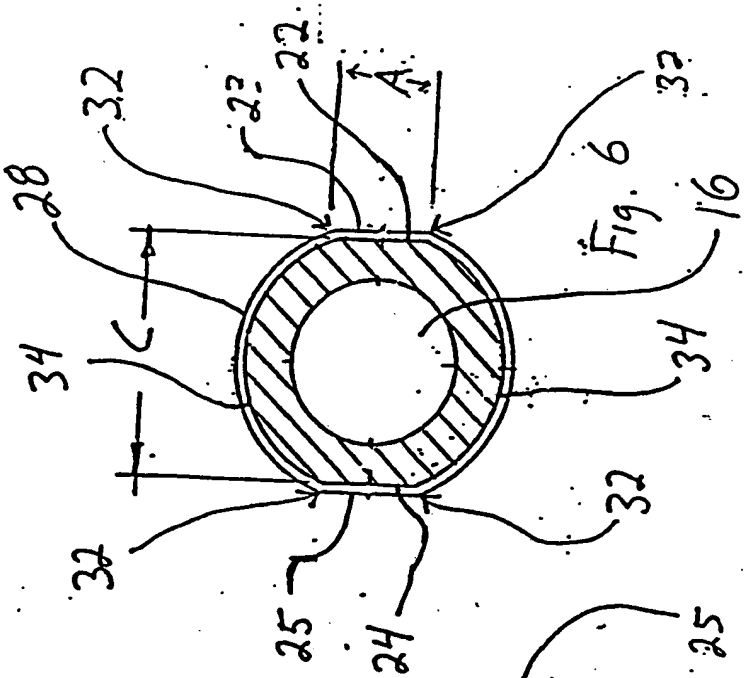


Fig. 6

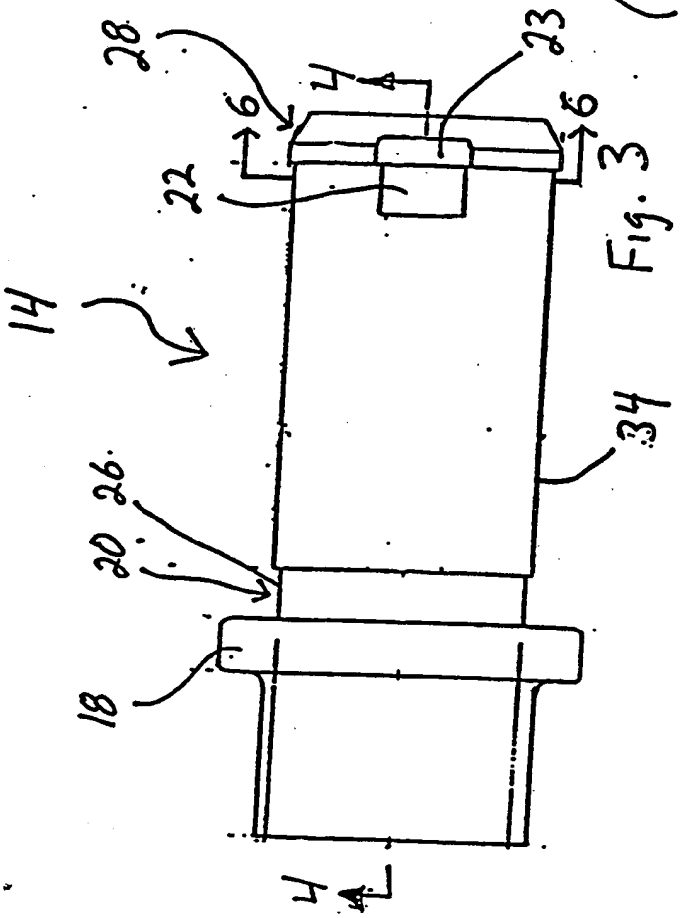


Fig. 3

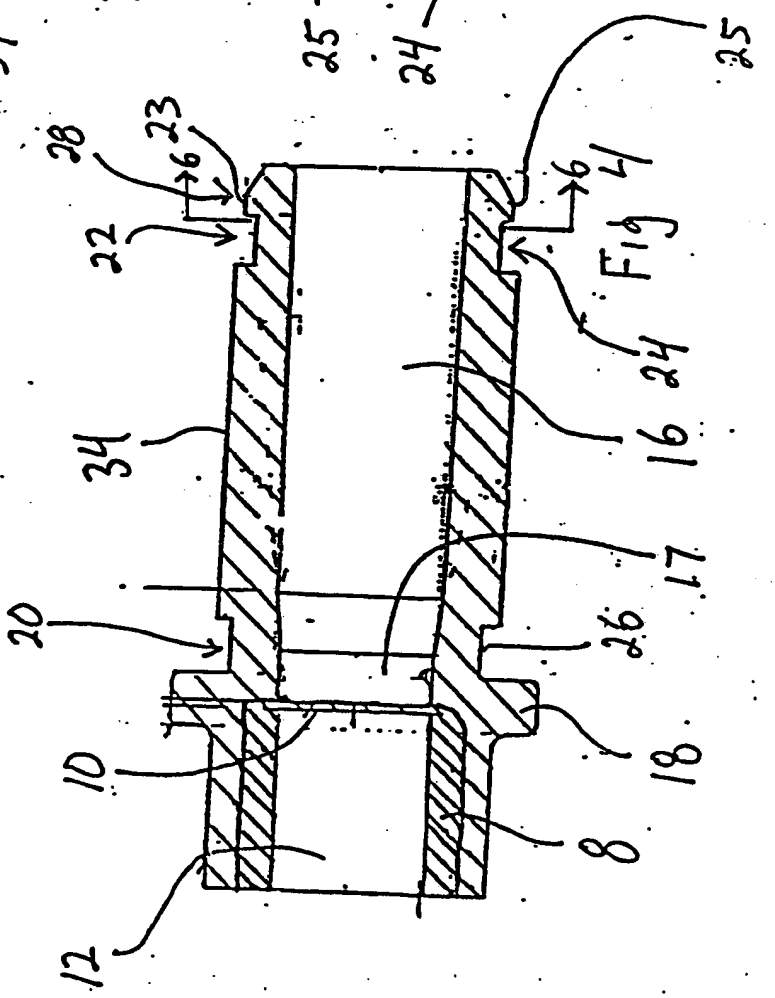


Fig 4

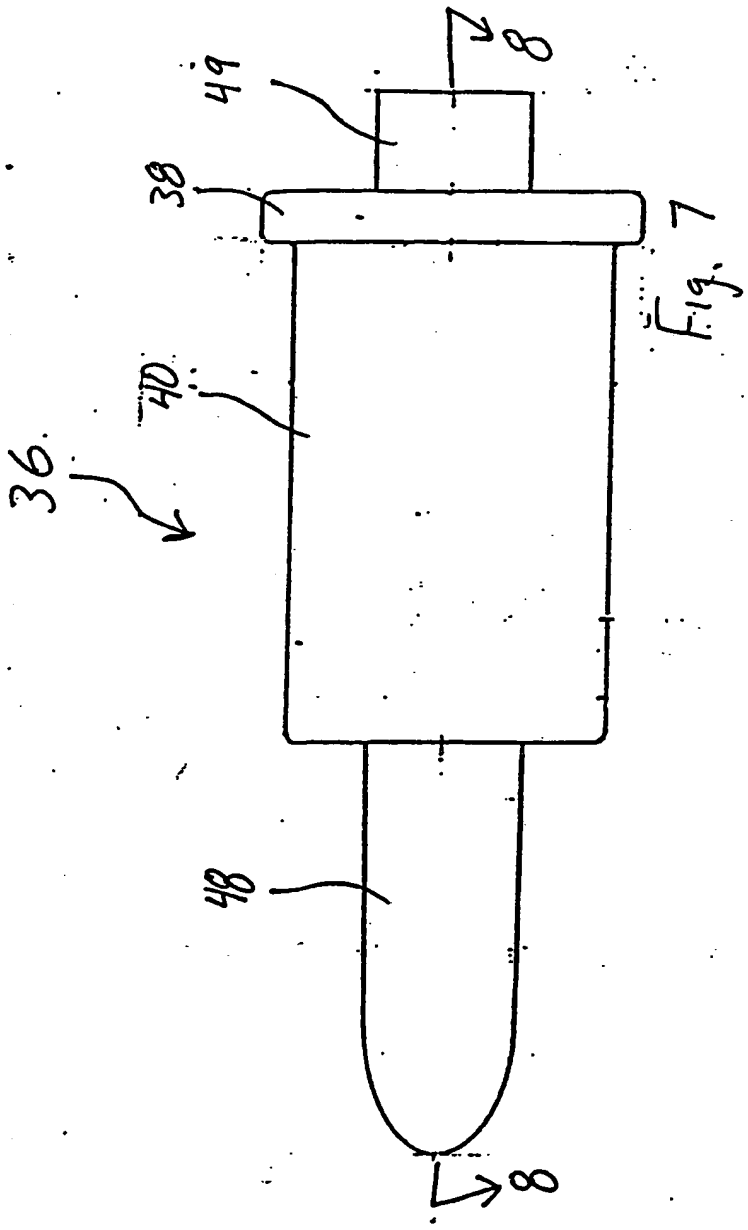


Fig. 7

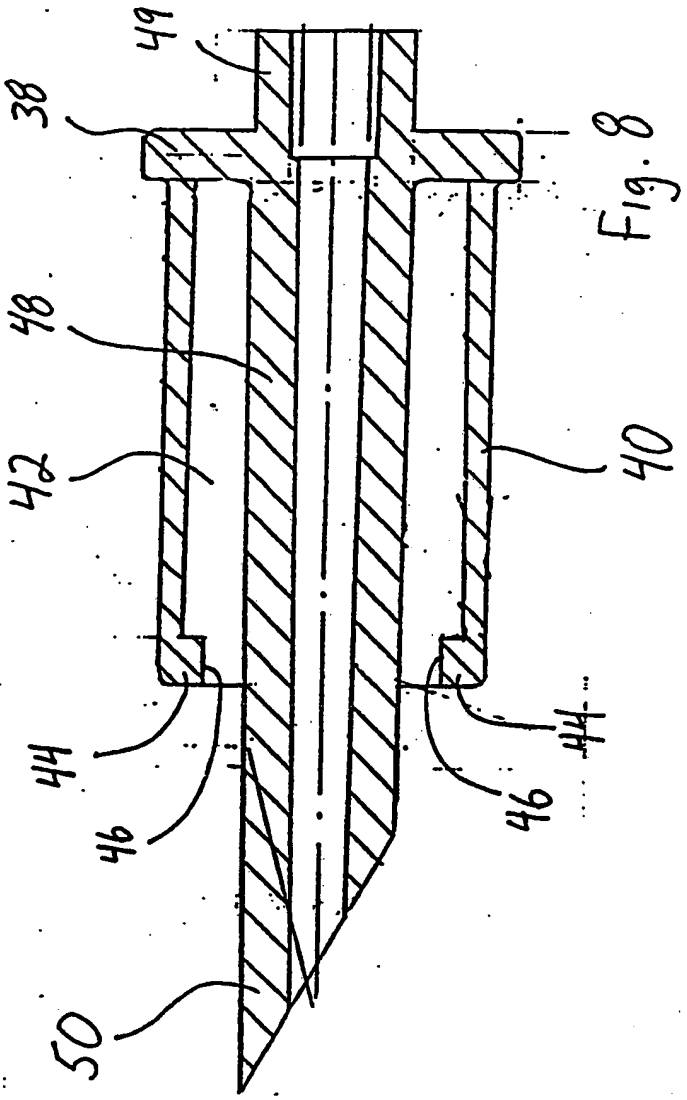


Fig. 8

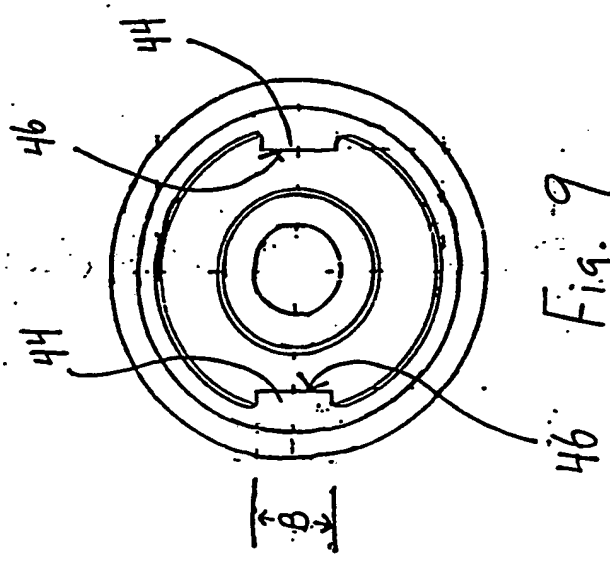


Fig. 9

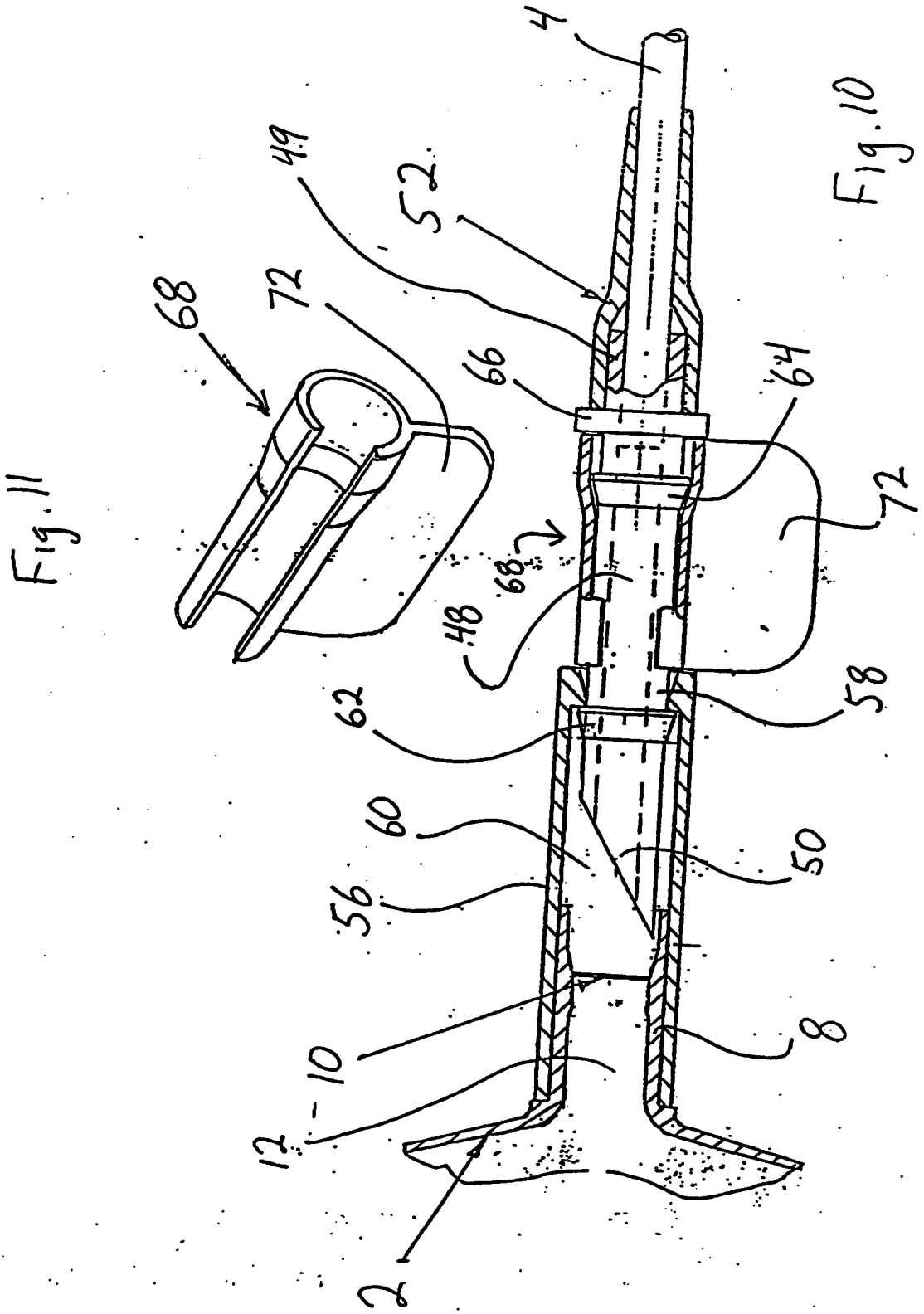


Fig. 10

Fig. 11

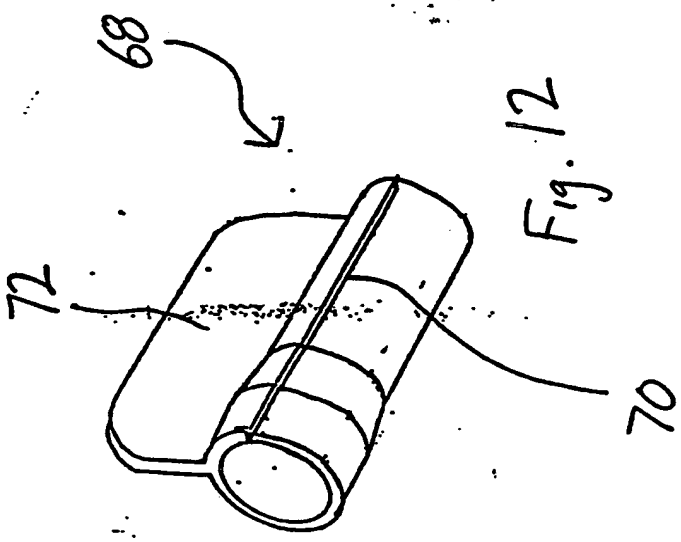
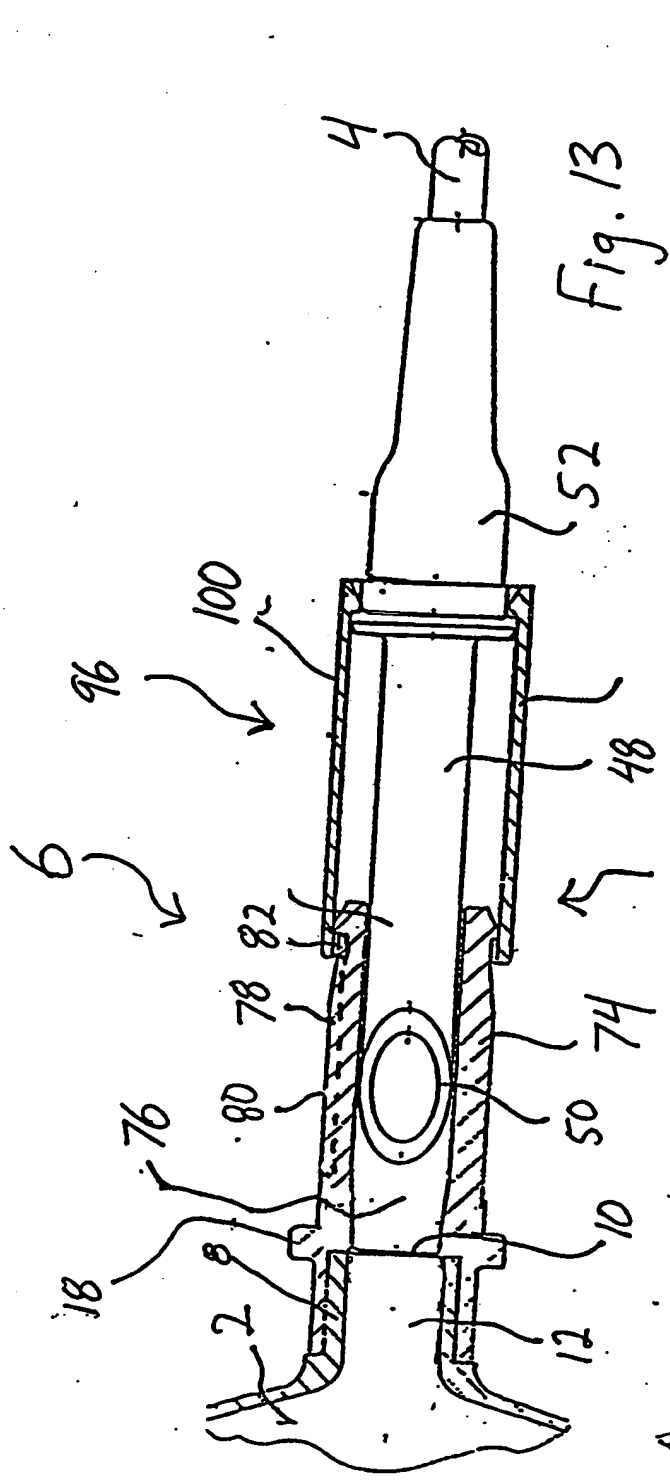


Fig. 12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76
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18
8
2
12

Fig. 13

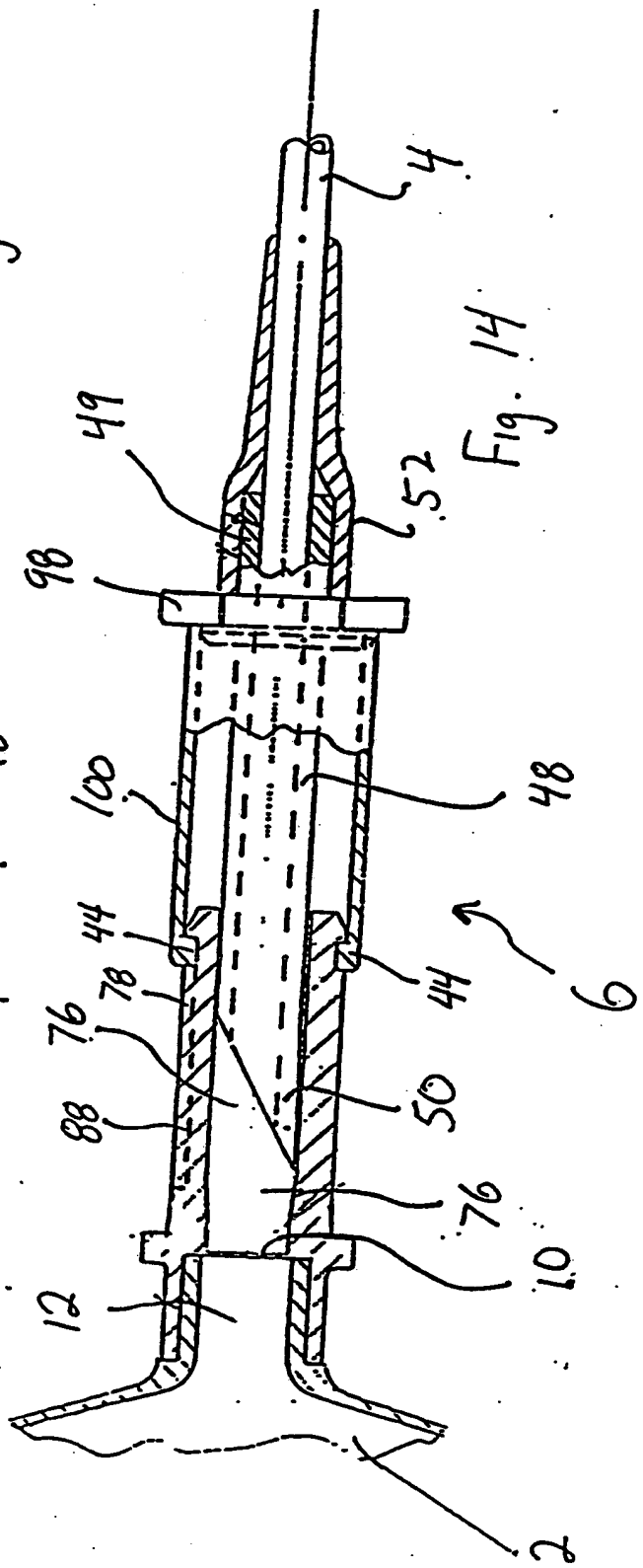
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Fig. 14

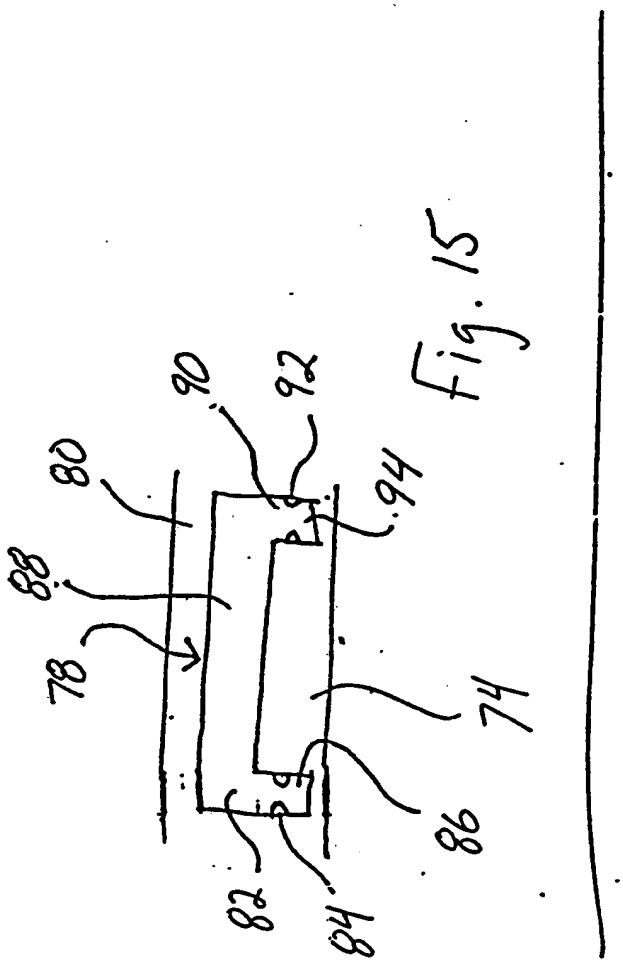
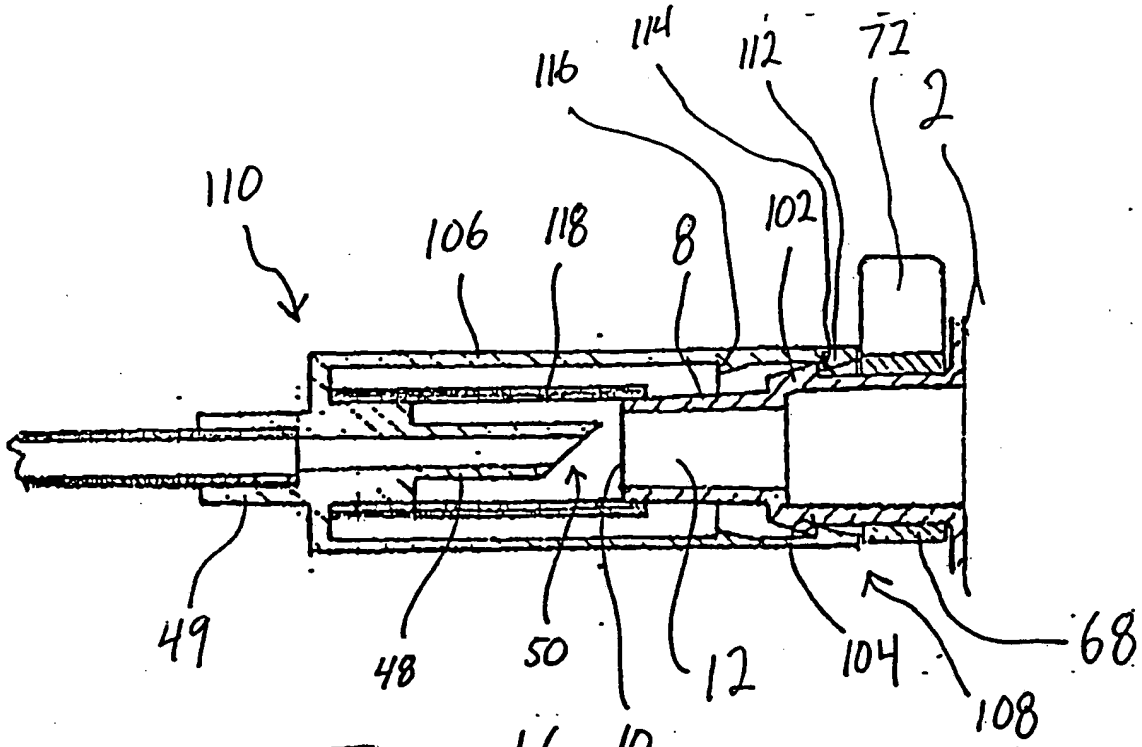


Fig. 15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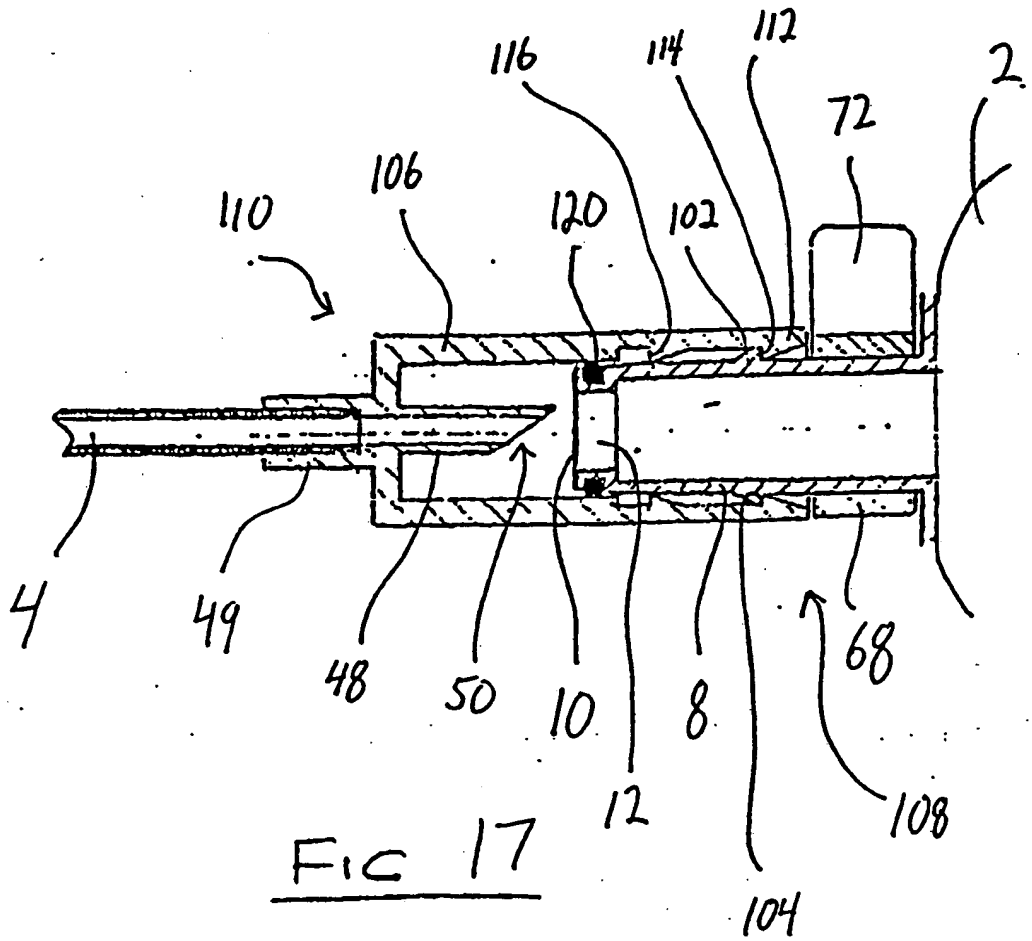
108
68

FIG 16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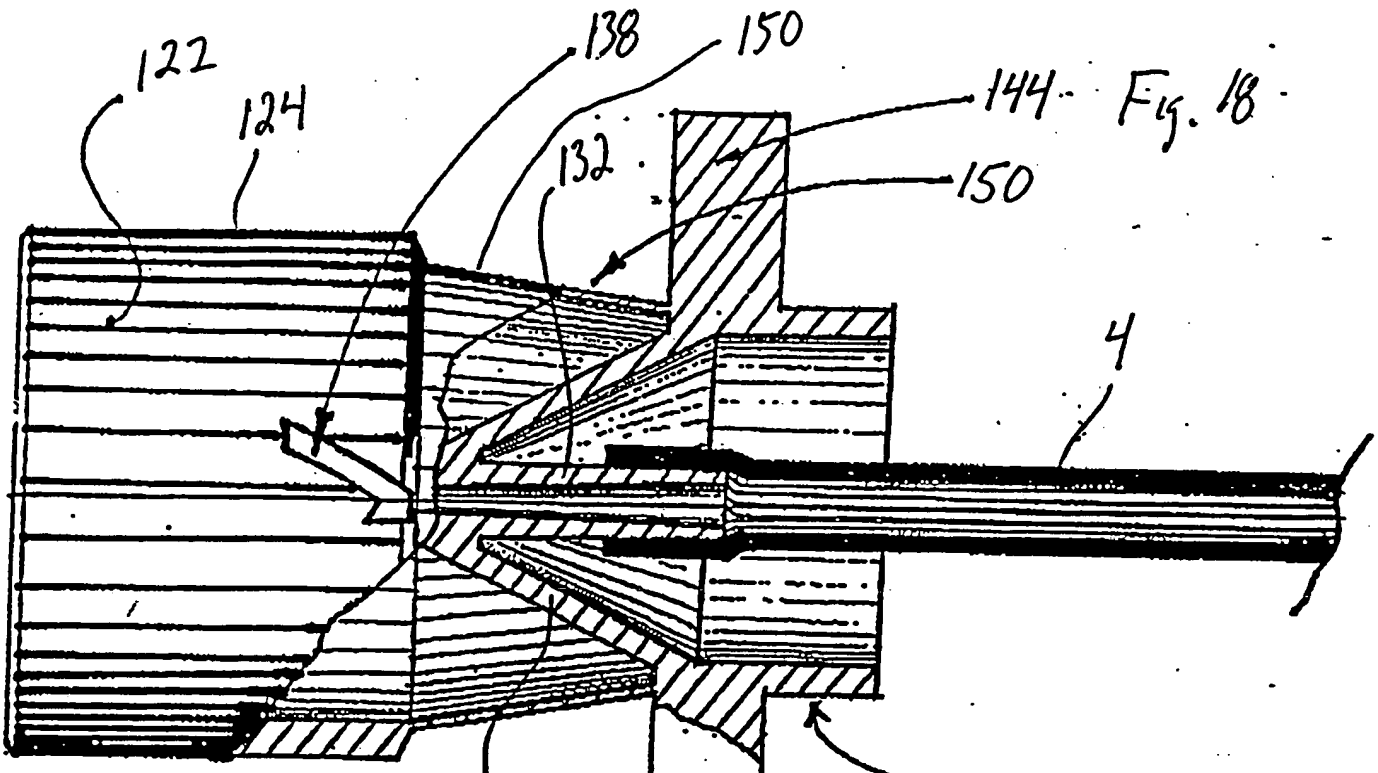
68
108

FIG 17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148
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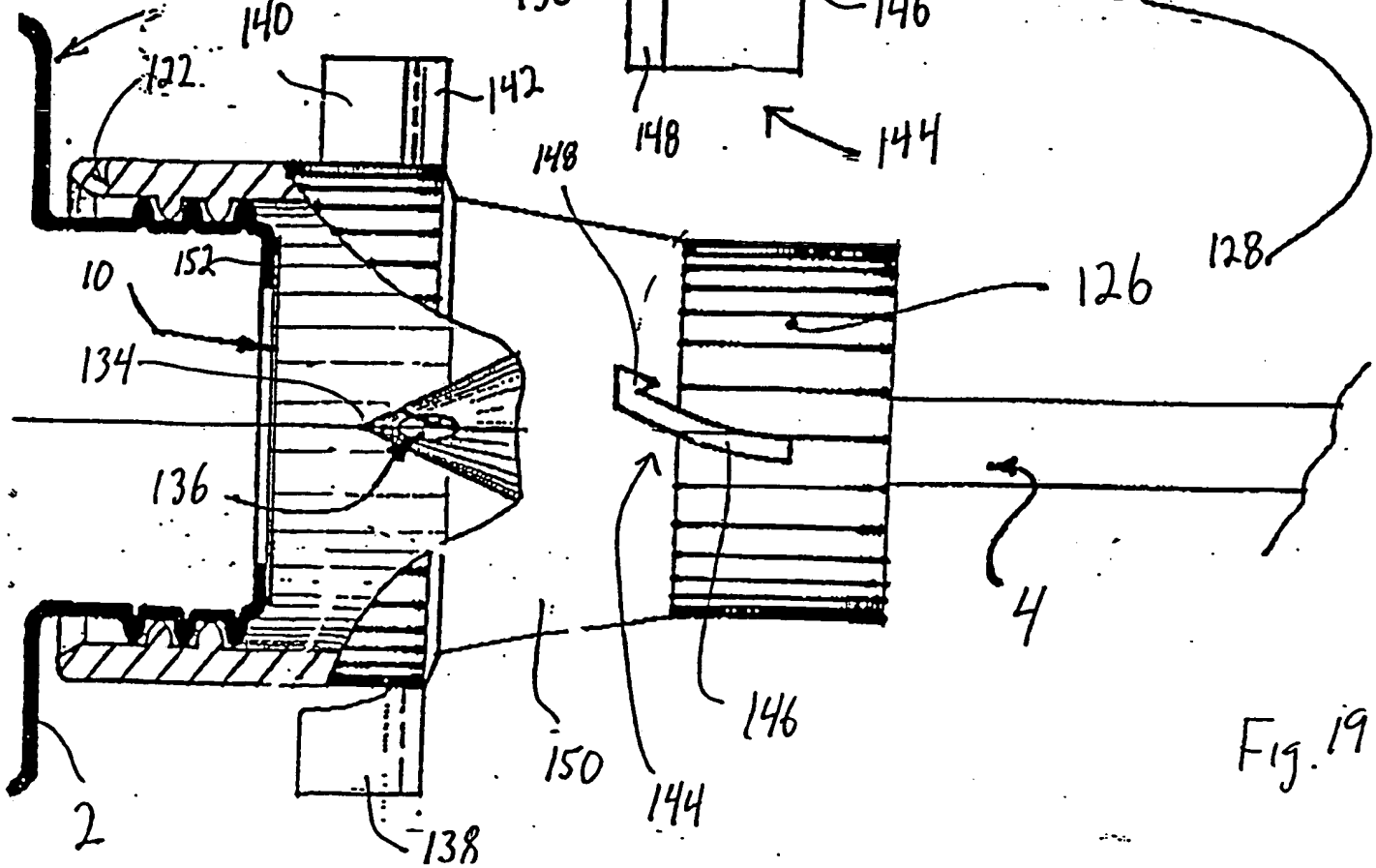
Fig. 18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148
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136
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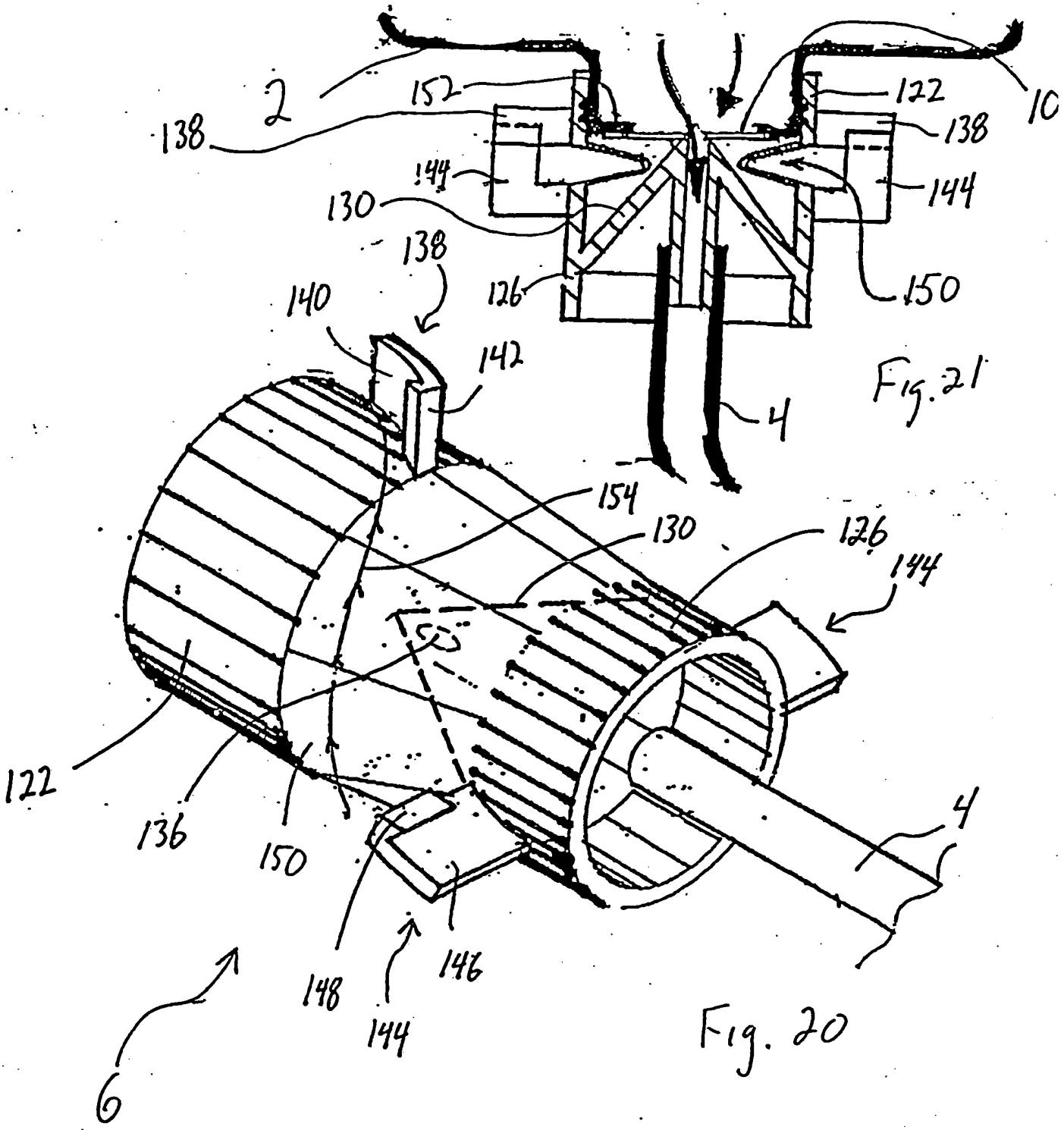
144
2
138

Fig. 19


2
152
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146
144
6

Fig. 21

Fig. 20

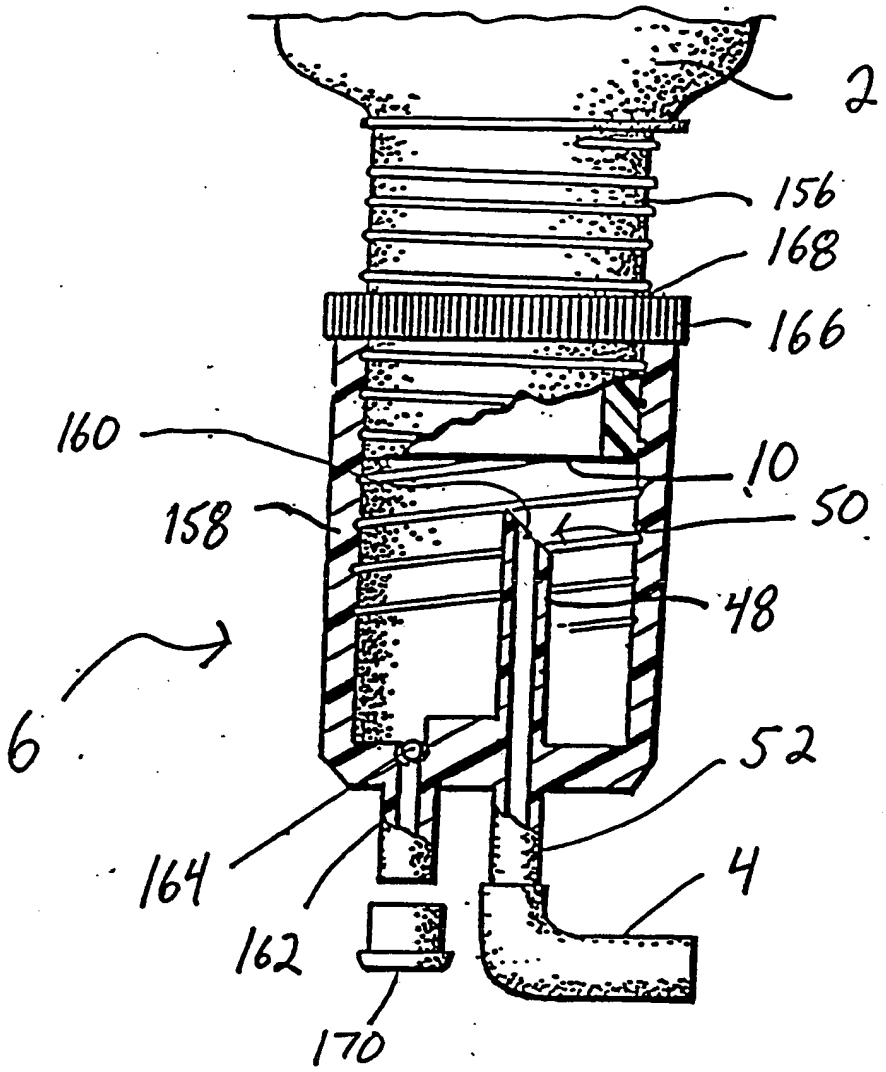

FIG. 22

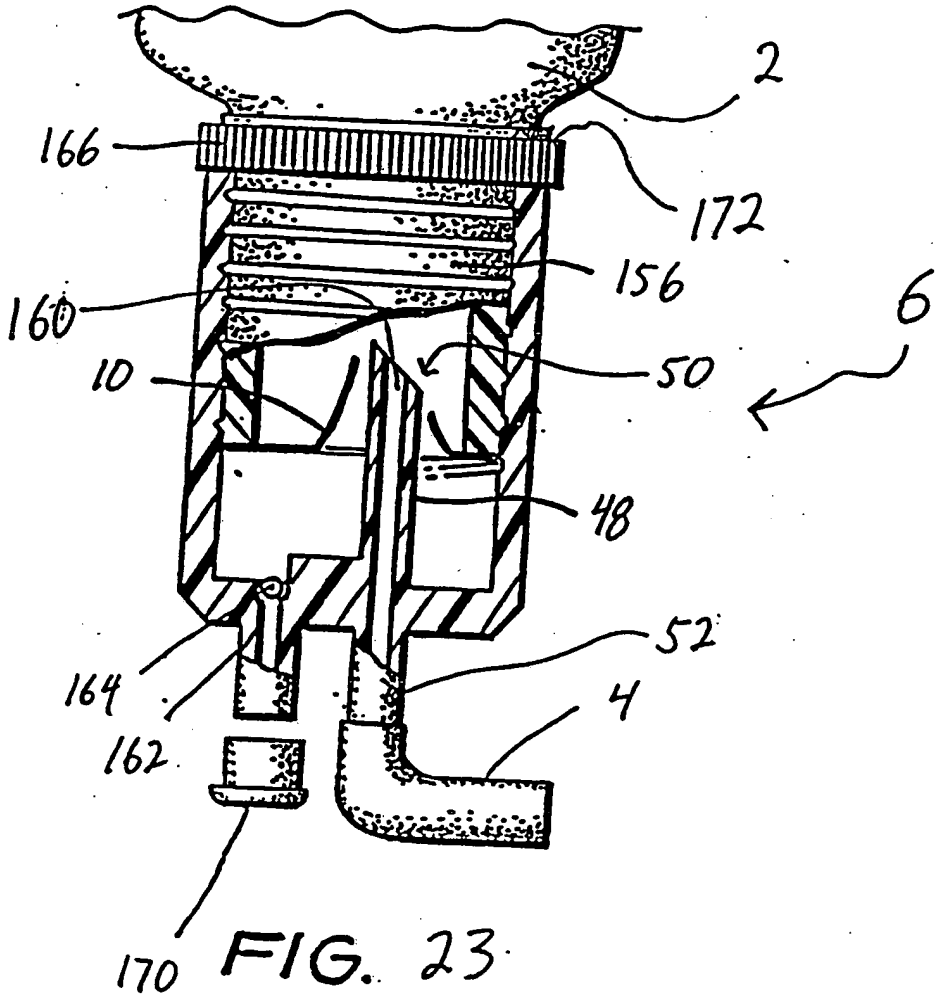

FIG. 23

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 19/00; A61M 5/32

US.CL :604/411

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/912,604/403,412-415,56,82-83 604/86-87,200-201,204-206

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A, 3,938,518 (Tischlinger) 17 February, 1976 See the figures.	1-36
Y	Us,A, 3,986,508 (Barringon) 19 October 1976, See the figures.	1-36
Y	US,A, 4,019,512 (Tenczar) 26 April 1977, See the figures.	1-36
Y	US,A, 4,161,949 (Thanawalla) 24 July 1979, See the figures.	1-36
Y	US,A, 4,201,406 (Dennehey et al.) 06 May 1980, See the figures.	1-36
Y	US,A, 4,381,776 (Latham, Jr.) 03 May 1983, See the figures.	1-36

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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

06 August 1993

Date of mailing of the international search report

02 SEP 1993

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Y,P	US,A, 5,195,994 (Dieringer) 23 March 1993, See the figures.	1-36
Y	US,A, 4,187,846 (Lolachi et al.) 12 February 1980, See the figures.	1-36

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